

EXHIBIT C

[Available at <http://scallyreview.ie/> (last checked on November 19, 2021).]

[Although the entire report is attached hereto as Exhibit C, relevant excerpts are highlighted for the Court's convenience.]

Scoping Inquiry into the CervicalCheck Screening Programme

Dr Gabriel Scally

**Final Report
September 2018**

Scoping Inquiry into the CervicalCheck Screening Programme

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Scoping Inquiry into the CervicalCheck Screening Programme

Foreword

Dear Minister,

This major crisis emerged into the public domain because of a failed attempt to disclose the results of a retrospective audit to a large group of women who had, unfortunately, developed cervical cancer. In particular, it emerged because of the extraordinary determination of Vicky Phelan not be silenced. But there are many indications that this was a system that was doomed to fail at some point. Screening services are sometimes finely balanced in terms of benefit and harm and can act as an early warning sign of wider systemic problems.

Unlike many similar problems in healthcare delivery, and screening in particular, it was impossible to narrow the focus to a few or even a small number of areas. The problems uncovered are redolent of a whole-system failure. The recognition of the problem as a whole-system failure meant that the Scoping Inquiry had to delve into the full range of issues that have impinged upon the cervical screening programme and this increased the complexity of my task. But it has also placed me in a good position to identify the changes which are needed to renew and strengthen the screening service.

The current policy and practice in relation to open disclosure is deeply contradictory and unsatisfactory. In essence, there is no compelling requirement on clinicians to disclose. It is left up to their personal and professional judgement. I know, very well, from very many of the women themselves and the families, that the issue of non-disclosure is felt very intensely. They have expressed very clearly their anger at not being told at the time when the information from the audit became available, and they are equally as angry about how they were eventually told. In my view, the manner in which they were eventually told of their situation in many cases varied from unsatisfactory and inappropriate, to damaging, hurtful and offensive.

It is apparent that there are serious gaps in the governance structures of the screening services. In the specific case of CervicalCheck, there was a demonstrable deficit of clear governance and reporting lines between it, the National Screening Service and the higher management structures of the HSE. This confusion complicated the reporting of issues and multiplied the risks. It is clear that there are also serious gaps in the range of expertise of professional and managerial staff directly engaged in the operation of CervicalCheck. There are, in addition, substantial weaknesses, indeed absences, of proper professional advisory structures. These deficiencies played no little role in the serious issues that concern this Scoping Inquiry.

I am satisfied with the quality management processes in the current laboratory sites i.e. CWIUH, Quest, and the Sonic Healthcare Laboratories, namely MLP and TDL. I am also satisfied that the quality management processes were adequate in the former provider, CPL in Austin, Texas, part of Sonic Healthcare.

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In August 2018, as a result of probing by the Scoping Inquiry, information was provided which indicated that slides from Ireland had been distributed by CPL to other laboratories to carry out at least part of the screening process. As detailed in the report, the Scoping Inquiry is now aware that slides were dealt with by laboratories in San Antonio and Victoria (both Texas), Honolulu (Hawaii), and Orlando (Florida). This information has only come to my attention in recent weeks. It clearly needs further and detailed examination, along with some closely associated issues of procurement and accreditation. I am happy to provide you with a supplementary report on these matters in due course.

But I want to be clear that CPL is not a current provider, and has not been since 2013, nor are any of the other laboratories to which they distributed slides. All of the laboratories visited by the Scoping Inquiry team are meeting the regulatory requirements current in their own country. There is abundant research evidence that screening sensitivity varies in different countries. As far as can be ascertained, all the laboratories have performance which is acceptable in their country.

There are many dedicated and experienced staff working in the screening services, including in CervicalCheck. Their skills and expertise should not be lost. With significant system change, effective leadership, improved clinical and public health medicine engagement, plus new and powerful patient advocacy, there is no reason why CervicalCheck should not deliver an outstanding service for the women of Ireland.

The continuation of cervical screening in the coming months is of crucial importance. My Scoping Inquiry team has found no reason why the existing contracts for laboratory services should not continue until the new HPV regime is introduced. This new approach of HPV testing will significantly improve the accuracy of the screening process, increasing the chances of more cancers being prevented due to the detection of early changes.

The challenging but exciting prospect of turning cervical cancer into a rare disease in Ireland will require a strengthened focus and skilled leadership. The CervicalCheck programme must take full advantage of the new testing process by working more effectively to reach out to the 20% of Irish women who do not yet take advantage of cervical screening. This, plus the welcome extension of the ever developing HPV vaccine to boys, creates a realistic prospect of the virtual elimination of cervical cancer in Ireland in the coming decades. This is a goal that I commend to you.

Public health programmes, like screening, vaccination, tobacco control or infectious disease surveillance, require a skilled and valued public health workforce. There was, unfortunately, limited public health medicine input into CervicalCheck and I firmly believe that was to its detriment. The time has surely come where public health physicians are accorded the same recognition as clinical colleagues and their skills deployed at the core of all public health programmes. I hope that movement on this matter can take place in the near future.

I am conscious that there are several important pieces of work taking place or in immediate prospect: The important task of Justice Meenan in making recommendations in relation to redress, the Royal College of Obstetrics and Gynaecology-led review of the screening slides, the commitment of the Acting Director General of the HSE to conduct an internal

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investigation following the publication of this report, and the limited amount of additional investigation that you have asked me to carry out into the use of additional laboratories.

Having considered the matter carefully, and reviewing the degree to which the Scoping Inquiry has managed to explore and clarify the key elements of the issues surrounding CervicalCheck, I have reached the view that a Commission of Investigation would not be the best way to proceed. In my personal view, there are two tasks that should now be given priority.

One is ensuring that the group of women affected, and the relatives of the deceased, are given the maximum amount of support in dealing with the difficulties that they now face arising from these complex and distressing events.

The second key task is in implementing the recommendations of this Scoping Inquiry. I am impressed by how your Department is carrying forward the recommendations of my first report and has included representatives of the women and relatives at the centre of its activities. There is a danger that a prolonged investigation, whilst it might further elucidate the matters that I have considered and correct any inexactitudes in this report, would consume valuable energy and resources that would be better devoted to the implementation of recommendations and achieving progress.

I would invite you to consider instead the commissioning of a review of progress, involving two specific elements:

- Within three months of the publication of the Scoping Inquiry report, there should be an independent review of implementation plans to be produced by each State body named in this report, in respect of the recommendations contained herein. The findings of this independent review of implementation plans should be submitted to the Minister and published.
- Thereafter, there should be a further review of progress reported to the Minister at six-monthly intervals and published.

I would suggest that the women and relatives affected should play a prominent part in the oversight of these reviews.

I would like to close by thanking all those who met with the Scoping Inquiry or supplied information, personal accounts, or advice.

Finally, I would like to thank all the members of the Scoping Inquiry team. They have achieved a remarkable task under difficult circumstances and with dedication and genuine concern for the difficult issues facing cervical screening in Ireland.

Yours sincerely,

Gabriel Scally

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Important Notice

When reading this report, it is important to bear the following in mind:

1. **This is a Scoping Inquiry and not a Commission of Investigation.**
2. **Information on which any conclusions or views are based is confined of necessity to the information that was furnished to the Scoping Inquiry. It has not been possible to offer each person or body who is named or referred to in the report an opportunity to comment on the report, or to canvass and represent views of all parties on every issue therein or on opinions expressed by other parties who met with the Scoping Inquiry.**
3. **All views expressed within the report are subject to the caveat that persons or bodies affected have not been given the opportunity to cross-examine or test the sources of information made available to the Scoping Inquiry, and the information, and hence the conclusions and views expressed as a result of the information, must therefore be treated with a certain degree of caution.**

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Glossary

Organisations

CervicalCheck	The national cervical cancer screening programme
CWUHU	Coombe Women & Infants University Hospital
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
ISCCP	Irish Society for Colposcopy and Cervical Pathology
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry Ireland
NCSS ¹	National Cancer Screening Service
NCSSB ¹	National Cancer Screening Services Board
NOCA	National Office of Clinical Audit
NSS ¹	National Screening Service
RCOG	Royal College of Obstetricians and Gynaecologists
SCA	State Claims Agency

Medical Terms

Asymptomatic	Where a disease is present but the patient has no symptoms
CIN	Cervical intra-epithelial neoplasia
Colposcopy	A detailed examination of the cervix using a colposcope
Cytology	The microscopic examination of cells
Cytopathology	The diagnostic technique that examines cells to determine the cause or nature of the disease
False negative	Samples where the test is originally reported as negative but on review abnormal cells are found
False positive	Samples where the test is reported as abnormal but the disease is not present
Histology	The study of the microscopic structure of tissues
HPV	Human papillomavirus, which can cause cervical and other cancers
Interval cancer	A cancer that is diagnosed clinically in the interval between screening tests
TBS	The Bethesda System: a system of classification of cervical cytology abnormalities

¹ The organisation now known as the National Screening Service (NSS) has previously been called the National Cancer Screening Services Board (NCSSB) and the National Cancer Screening Service (NCSS) at different times since its establishment, as set out in more detail in Section 5. Throughout this document, references may variously be made to the different names of this entity depending on the period of time being referred to within the text in question.

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TIS	ThinPrep Imaging System – a computer assisted microscopy system for identifying abnormal cells on cervical cytology slides
True negative	Samples which genuinely have no abnormal cells on them, despite the presence of disease
True positive	Samples where genuine disease is detected

Other Terminology

Framework contract	A procurement process whereby a number of suppliers compete for inclusion in a restricted list, whose members will then be invited to tender for specific contracts via 'mini-competitions'
ISO 15189	International standard in respect of quality and competence requirements particular to medical laboratories
ISO 9001	International standard in respect of quality management systems
KPIs	Key Performance Indicators
MoU	Memorandum of Understanding
NHS	National Health Service (Britain)
PQQ	Pre-Qualification Questionnaire
QA	Quality Assurance
RFP	Request for Proposals
SOP	Standard Operating Procedure

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1 Introduction

1.1 Establishment of the Scoping Inquiry / Terms of Reference

On the 8th May 2018, the Cabinet agreed to establish a Scoping Inquiry into the issues which had recently come to light in relation to the CervicalCheck screening programme and I was appointed to carry out the Scoping Inquiry. I was tasked with reporting to the Minister for Health pursuant to the following terms of reference:

- a) examine the facts including details of:
 - i) The non-disclosure of information to Ms. Phelan relating to a CervicalCheck standard case clinical audit carried out following her diagnosis of cervical cancer in July 2014;
 - ii) The apparent widespread practice of non-disclosure to patients relating to CervicalCheck standard case clinical audits;
 - iii) The management and level of knowledge of various parties including, but not limited to the HSE, the Department of Health or other public authorities and any relevant service provider of:
 1. the Vicky Phelan case
 2. any other cases concerning CervicalCheck
 3. issues related to the non-disclosure of the clinical audit results
 - iv) The manner and means through which the relevant facts were shared, escalated, reported and communicated;
- b) engage directly with Ms. Phelan and any other woman affected or her next of kin, who may wish to have an input;
- c) examine all aspects of CervicalCheck;
- d) examine the information provided by CervicalCheck to those receiving a service;
- e) examine why the policy of open disclosure was not implemented by CervicalCheck;
- f) examine the tendering, contracting, operation, conflict of interest arrangements, performance information and performance management, accreditation and quality assurance of contracted cytology laboratory services by CervicalCheck from initiation of the programme;
- g) examine the other screening programmes operated by the National Screening Service particularly in relation to quality assurance and clinical audit, open disclosure and governance;
- h) incorporate further elements if identified, including through engagement with stakeholders;
- i) have flexibility to issue discrete reports or findings on particular matters if it is in a position to do so and provide a progress update in the first week of June;
- j) report to the Minister for Health by the end of June 2018 setting out issues and recommendations to be addressed by means of a Commission of Investigation,

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which can take a modular approach, together with recommendations to address other issues by such other means as is considered appropriate.

1.2 Scoping Inquiry Team

1.2.1 Overview

In order to undertake the Scoping Inquiry, I appointed a number of advisors to assist in the work programme and to carry out specific tasks relating to their professional expertise. A brief outline of their role and experience is provided here.

1.2.2 *Dr Karin Denton*

Dr Karin Denton provided advice on screening quality assurance. Dr Denton is a Consultant Cytopathologist at North Bristol NHS Trust and has had substantial involvement in the quality assurance of cervical screening programmes at a senior level in England.

1.2.3 *Dr Hugh Annett*

Dr Hugh Annett provided advice on quality assurance and clinical audit, open disclosure, and governance in screening services other than cervical screening. Dr Annett is a former Director of Public Health in England and has wide international public health experience.

1.2.4 *Professor Julia Verne*

Professor Julia Verne provided advice on cancer registration. Professor Verne is a consultant in public health medicine and is currently Head of Clinical Epidemiology for Public Health England. She was previously head of the South West Public Health Observatory, with responsibility for cancer registration.

1.2.5 *Mary Rose Gearty, S.C. and Emer Woodfull, B.L.*

Mary Rose Gearty and Emer Woodfull provided invaluable legal and practical advice at the outset of this Scoping Inquiry as to its remit, its priorities, and the powers and limitations of my role. They have been influential in shaping the approach to this work. Both have extensive legal experience but in particular in the field of investigative and quasi-judicial tasks and the relevant principles of law which apply to such work.

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1.3 Support to the Scoping Inquiry

1.3.1 Crowe

Crowe (formerly Crowe Horwath) is a professional advisory firm based in Dublin and part of the Crowe Global network. They provided logistical, project management, and analytical support to this Inquiry. In addition, Crowe provided office and meeting space together with administrative support for the Scoping Inquiry.

The Crowe team provided specific expertise in the fields of procurement, contracting, governance, and related matters.

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2 Method of Approach

2.1 Organisation of the Scoping Inquiry

Recognising the scale and complexity of the requirements set out within the terms of reference, the work of the Scoping Inquiry was structured into a number of different areas of focus:

- Non-disclosure to patients relating to CervicalCheck standard case clinical audits and related matters;
- The operational functioning of the CervicalCheck service, including clinical, scientific, management, governance, and administrative matters;
- The tendering, contracting, and operation of the cytology laboratory services contracted by CervicalCheck, including accreditation and quality assurance;
- Governance issues in respect of the oversight of CervicalCheck, including the National Screening Service (NSS), the Health Service Executive (HSE), and the Department of Health (the Department);
- Issues relating to cancer registration and the relationship between cancer registration and screening services;
- An overview of the other screening programmes under the National Screening Service.

A key element of this review has been to listen to the voices of the women and families affected by the issues involved. Throughout this report, direct quotes have been included, highlighted in shaded boxes, from the women and the family members directly impacted by these issues. I believe that these serve to highlight the real, lasting damage done to these women and their families and to ensure that their voices are heard.

2.2 Overview of Approach

The work of the Scoping Inquiry was informed by a number of key tasks and activities:

- Engagement with women and families affected: from the outset, I and other members of the Scoping Inquiry team have engaged with the women and family members involved in these issues, by means of email, telephone, face-to-face meetings, and group meetings. This engagement has been key to identifying what happened and how it affected those who were impacted.
- Reviewing over 12,800 documents supplied by individuals and organisations involved, including the HSE, the Department of Health, the National Cancer Registry Ireland, the State Claims Agency, laboratories, and others.
- Interviewing key personnel, individually and in groups, from the organisations concerned: CervicalCheck, the National Screening Service, the HSE, the Department of Health, the State Claims Agency, the National Cancer Registry Ireland, and the laboratory service providers.

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- Visiting laboratory facilities where CervicalCheck screening tests were analysed.
- Reviewing best practice internationally in respect of cancer screening, cancer registry, screening audit, and disclosure policies.
- Analysing the information gathered and developing findings and recommendations as set out in this final report to the Minister for Health.

2.3 Timescales for the Scoping Inquiry

The initial timescale for submission of a report to the Minister for Health was the end of June 2018. Central to this work was the need to engage with as many women and families directly affected as possible, which led to a number of group meetings being held during June and July, along with continuous engagement via phone and email including up to September.

The difficulties in accessing timely and readable documentation is already well known. Working through all of the complex issues, reviewing the 12,800+ documents received up to and including 5th September, and the need to have further meetings and engagement with various interested parties also required significant time and space in order to develop an informed report.

Given the volume of work that was required in order to meet the Terms of Reference, it was necessary to extend the initial timescale until the end of summer.

2.4 Communication

A Scoping Inquiry website was created at www.scallyreview.ie This website included information on:

- Terms of reference of the Scoping Inquiry;
- Statement of Work;
- Biographical details;
- Declarations of Interests for members of the project team;
- Contact details for the Scoping Inquiry.

A dedicated email address, scallyreview@crowehorwath.ie, was created to allow women/families affected to get in direct contact with the Scoping Inquiry.

2.5 Management of Information/Documentation

A key element of the Scoping Inquiry was the requirement to review the extremely large body of documentation relating to the terms of reference.

Requests were issued to the Department of Health, the HSE, the State Claims Agency, the National Cancer Registry of Ireland, and other entities, for a range of documentation, including in respect of the following:

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- The case brought by Vicky Phelan and related cases;
- CervicalCheck's structure and operations, policies and procedures, and information dissemination to patients;
- The contracting out of cytology services by CervicalCheck;
- Other cancer screening programmes;
- Governance and communications involving the HSE, the Department of Health, and other relevant State agencies / interested parties.

In addition, the Scoping Inquiry was given documentation and information from women and family members affected, in relation to their own cases, such as clinical information, examples of communication between clinicians and the HSE, and legal advice.

The Scoping Inquiry sourced documentation available online such as published reports and other publicly available information of relevance to the terms of reference.

ELECTRONIC DOCUMENT REVIEW

TOTAL  DOCUMENTS RECEIVED:

12,837

DoH:
6,958

HSE:
5,494

SCA:
380

NCRI:
5

DoH = Department of Health
SCA = State Claims Agency

HSE = Health Service Executive (including CervicalCheck)
NCRI = National Cancer Registry, Ireland

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There were significant and frustrating difficulties in the early stages of the Scoping Inquiry in respect of the timely receipt of all requested documentation in the appropriate format. Following a series of communications with the key stakeholder organisations, the Scoping Inquiry was given access to an electronic document management platform which was used both to supply key documentation to the Scoping Inquiry and to support the review and management of this documentation to enable the Scoping Inquiry to utilise the information within.

During the prolonged discovery stage of the Scoping Inquiry, over 12,800 documents were received, up to and until 5th September (the day before the submission of this report to the Minister). It is clear that there is work to be done in improving the document management system within the health system. As noted above, the team received documents initially in a wide variety of formats, some of which were unreadable and many of which were unsearchable using electronic search tools. In some instances, the Scoping Inquiry was provided with documents which had originally existed in soft copy but had been printed and scanned, thus reducing the quality of the documents and removing the potential to use electronic search tools.

2.6 Recommendation

- 1) The Department of Health and the HSE should revise their policies in respect of document management. This should ensure that good quality records are created and maintained which are authentic, reliable, and complete in searchable format. They should be protected and preserved to support future actions and ensure current and future accountability.

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3 Cervical Cancer and Screening

3.1 Background

Cervical cancer occurs in the cervix, or neck of the womb. As with all cancers, abnormal cells have the ability to invade the area where they are located and spread to other parts of the body. Typically, the disease can be quite advanced before a woman experiences any symptoms. That is why prevention and early detection are so important in the early pre-cancerous stages.

Cervical cancer is the fourth most common cancer in women worldwide and there are over half a million cases diagnosed every year. In Ireland in 2015 (the most recent year for which data is published), there were 241 cases of cervical cancer. This means the lifetime risk of a woman getting cervical cancer was 1 in 135. In 2007, the year before the cervical screening programme started, the lifetime risk was calculated as 1 in 96. This represents a substantial improvement.

Overall, it is generally accepted that cervical screening and breast screening can prevent some, but not all cancers. The NHS screening service states:²

It is estimated that cervical screening prevents 75% of invasive cervical cancers by detecting and treating cervical abnormalities that, if left, would place patients at high risk of developing invasive cervical cancer.

And in respect of breast cancer screening it states:

It aims to prevent 25% of breast cancer deaths in patients in this age group by detecting and treating breast cancers at an early stage before symptoms are apparent.

3.2 Screening Programmes

‘Screening’ is the method used to detect a disease, or possible early signs by means of a test or examination for people who have no obvious clinical indications or symptoms. A ‘screening programme’ is a system for applying the test, or examination to the population at risk. Screening programmes often include public education efforts, as well as call and re-call systems, and the clinical services needed for the further investigation and treatment of people identified as at risk of having, or developing, the disease.

All screening programmes are a balance of benefit and disbenefit (i.e. harm). On the one hand, identifying a disease at an early stage usually allows for more effective treatment and its possible eradication. On the other, some screening procedures and

² NHS Cancer Screening Programmes. Disclosure of Audit Results in Cancer Screening: Advice on Best Practice. 2006. p1.

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subsequent investigations carry risks to the patient, such as a low-level radiation dose or damage from medical instruments. Further disbenefits can arise from results that give false reassurance where the disease is present but the screening wasn't able to identify it, or cause stress where the screening indicates that there might be a problem but no actual disease is found.

Therefore, a screening programme must satisfy a number of criteria before it is introduced, including a requirement that 'the overall benefits of screening should outweigh the harm'.³ In the case of cervical cancer, there is clear and undisputed evidence that properly-run screening programmes are of substantial benefit to the female population of the State.

3.3 Latent Period

One of the original criteria for a screening programme is that the disease should have a reasonably long latent period, when there are no symptoms of any significance but it is detectable by a test.⁴ With cervical cancer, progression from the pre-invasive to the invasive stage takes a relatively long time, i.e. up to 10 or 15 years. This means a test performed regularly, typically every three years, will stand a very good chance of detecting the early signs.

3.4 Cervical Cancer Screening Tests

One of the other requirements for a screening programme is that there should be a suitable test that is acceptable to patients. The main test used throughout the ten years of the screening programme is based on examination by professionally trained laboratory staff (cytologists) of a sample of cells taken from the woman's cervix by a health professional. This test is known by different names. It was originally developed by a Greek cytopathologist, named Georgios Papanikolaou, who, in the early 20th century, discovered that it was possible to diagnose cervical cancer by looking at a sample of cells obtained from the cervix. Consequently, it became known as the 'Pap smear'. The means of collecting and examining cells from the cervix has developed in recent decades and the test is also called a 'cervical smear' or 'cervical test'. The core science for this approach is the medical specialty of cytopathology.

The Human Papilloma Virus (HPV) is responsible for causing a substantial majority of cervical cancers; as well as causing a range of other cancers such as throat, penile, and anal cancer. There are over 100 types of HPV virus, but only a few, referred to as 'High Risk Types' lead to the development of cervical cancer. Usually, when infected by a virus the body's own defences manage to clear it completely with no symptoms or effects. But sometimes the virus persists and is responsible for the cellular changes that, if not treated, can lead to invasive cervical cancer.

³ Andermann A, Blancaert I, Beauchamp S, Déry V. Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years. *Bulletin of the World Health Organization*. 2008; 86:317-9.

⁴ Wilson JM, Junger YG. *Screening for disease*. Geneva: World Health Organization. 1986.

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Taking and testing a sample from the cervix is now a straightforward and very accurate process. The test, which is performed by a machine, detects the presence of components of the High Risk HPV virus (DNA or RNA) in very small amounts. A positive test doesn't mean that cancer, or even changes that might lead to cancer, are present, but it does indicate that further tests or examinations might be warranted. The HPV test is used currently in the screening programme when abnormalities are detected by the traditional cervical test and as a test following treatment. However, starting in 2018, the plan is to make it the primary test for the cervical screening programme.

3.5 Comparing the Two Tests

It is generally recognised that the best quality analysis of current medical evidence is produced through the Cochrane Systematic Review process. In 2018 Cochrane published a review of the evidence from 40 studies comparing the traditional cytology test with the newer HPV test.⁵ It must be noted that the studies included are from around the world and, as the authors acknowledge, 'tests were more accurate in studies in Europe than in Asia or Central or South America'. Nevertheless, they concluded that there were advantages with the HPV test because a negative HPV is more reassuring than a negative smear. However, a HPV test will lead to more unnecessary referrals for further investigation.

The review put the comparison between the two testing approaches very clearly:

This review found that for every 1000 women screened, around 20 women will have precancerous changes. The HPV test will correctly identify 18 of these women (but will miss 2 women). The Pap test will identify 15 of the women (but will miss 5 women). The women who are missed could develop cervical cancer.

For every 1000 women screened, there will be 980 women who will not have precancerous changes. The HPV test will correctly identify 881 women (but 99 women will be incorrectly told that they have a lesion). The Pap test will correctly identify 885 women (but 95 will be incorrectly told that they have a lesion). Women who are incorrectly told that they have a lesion may have their cervix examined or may receive surgery unnecessarily.

This excerpt from the review encapsulates the concepts of 'sensitivity' and 'specificity' and how they apply to the two cervical screening tests. Sensitivity refers to the test's ability to correctly detect the condition in people who have it. Specificity relates to the test's ability to correctly identify people who don't have the condition. But when using these figures, particularly the one for 'sensitivity', it needs to be borne in mind that this is just for one single smear reading, or a single HPV test. No

⁵

Koliopoulos G, Nyaga VN, Santesso N, Bryant A, Martin-Hirsch PP, Mustafa RA, Schünemann H, Paraskevaidis E, Arbyn M. Cytology versus HPV testing for cervical cancer screening in the general population. The Cochrane Library. 2017 Jan 1.

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screening test yet developed can deliver 100% sensitivity although multiple cytological examination of one slide will improve sensitivity, i.e. the rate of detecting cancerous cells. So too will performing screening tests at regular intervals (e.g. three years); thus delivering a higher 'longitudinal sensitivity' than the sensitivity achieved by a once-off test.

HOW DOES THE NEW HPV TEST COMPARE WITH THE TRADITIONAL CERVICAL TEST?



Around 20 women will have precancerous changes.

18 The HPV test will correctly identify 18 of these women

15 The traditional cervical test will identify 15 of the women

3.6 True Positives and Negatives, and False Positives and Negatives

Tests results are often referred to as being positive and negative. The terms 'true' and 'false' are sometimes attached to the result. But great care is needed in the use of these terms as they may be applied in different ways. In the context of retrospectively reviewing slides in cases where there is a definite cancer diagnosis confirmed by histology, true negatives are samples which genuinely have no abnormal cells on them, despite the presence of disease. False negatives are those where the slide was originally reported as negative but on review abnormal cells are found. Some screening programmes then divide those false negatives into one of two groups:

1. Abnormalities that most screeners would not have detected.
2. Abnormalities that most screeners would have detected.

It is often a matter for professional judgement and discussion into which of these two groups any single false negative will fit.

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“I completely understand that there will always be a percentage of false negatives in any screening process”

3.7 Interval Cancer

An interval cancer is described, at its simplest, is one that is diagnosed clinically in the interval between screening tests. It is good practice in screening programmes to look back at the screening history to see if there were things in the screening that could have been done differently that might have helped detect the cancer earlier. This might be anything from the call and recall procedure, such as missing an address change or offering an inconvenient screening appointment, to a human error in reading a test such as a cervical smear or, in breast screening, interpreting a mammogram.

3.8 Review Bias

Conducting an audit or review of interval cancers is, as stated above, a good thing to do for the purposes of quality control and, particularly, learning. But it is not without problems when it comes to comparability. These difficult issues have been summarised in the following bullet points from a document produced by the NHS screening programmes in Britain in 2016:

- *No matter how closely the review panel tries to reproduce the original screening conditions, the conditions of a review are different – the fact that a review includes records of a patient known to have a serious condition, such as cancer, will heighten vigilance and increase reports of abnormality*
- *Finding discrepancies on review does not imply that the same findings should have been made under routine conditions.*
- *Hindsight has a significant impact on the interpretation of images.*
- *In a number of screening programmes, such as fetal anomaly ultrasound, cervical and breast screening, the result is based on interpretation of appearances on a scan, slide or mammogram in circumstances where the boundary between normality and abnormality is not firmly drawn – this may result in debate between experts as to the appropriate classification of the sample or the interpretation of the image.⁶*

3.9 Classification of Slide Results

The result classification system that is in general use in Ireland is The Bethesda System (TBS) terminology. It is, because of the nature and variation of the disease,

⁶ Public Health England. Guidance on applying Duty of Candour and disclosing audit results. V1.0. September 2016. p16.

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complex and difficult to grasp unless one is immersed in the subject. But because it is used in various sections of the report, often in abbreviated form, it is introduced here.

Cervical cytology samples can be classified as follows:

- Negative
- Atypical squamous cells of undetermined significance (ASCUS)
- Atypical squamous cells cannot exclude HSIL (ASC-H)
- Low grade squamous intraepithelial lesion (LSIL)
- High grade squamous intraepithelial lesion (HSIL)
- Squamous cell carcinoma
- Atypical endocervical cells
- Atypical endocervical cells, favour neoplastic
- Endocervical adenocarcinoma in situ
- Endocervical adenocarcinoma

This list is abridged from the full, more extensive, classification.

There are also rarely-used categories for adenocarcinoma of other types. In all cases, the microscopic appearances which lead to classification in one of these categories are fully described and widely published.

The nature of cervical premalignant disease means that cervical cytology is not always diagnostic of the worst abnormality present, so that for example a patient with a result of LSIL might in fact have HSIL. This is the rationale for further investigation as described in this section.

3.10 Analysis

Cervical screening is, like other screening programmes, dependent not only on the medical science involved in diagnosing and treating individual patients, but on the public health and clinical science involved in designing, managing and evaluating a complex programme that operates on a huge scale. Although the benefits of a well-resourced and efficiently run cervical screening programme are substantial, it does not yet provide the complete answer to preventing, accurately detecting and effectively treating all cases of cervical cancer. Just as there are limitations of screening, so too are there limitations of audit and review. Where judgements are being made, they must be made taking both of these factors into account.

“I have four daughters and one son who were shocked by this too, I will always encourage my girls to have smears and I hope the system is fixed so they don’t ever feel as let down as I was.”

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4 Listening to the Voices of the Women and Families Affected

"I know in my heart she would have wanted to know."

(Husband of one of the deceased women)

4.1 Background

At the heart of this Scoping Inquiry are the women and families affected by cervical cancer, the CervicalCheck audit and disclosure. Therefore, a central feature of the Scoping Inquiry was to engage with as many women and families affected as wished to do so. Some women did not wish to engage. They had a variety of reasons: some had closed the door on a painful and traumatic episode; some had not told anyone, even their families; some were scared that they might become the subject of press reporting and intrusion. However, very many people did get involved, and made an invaluable contribution to the Scoping Inquiry's work.

Each woman's experience, and that of her family is unique, and it was important that the Scoping Inquiry was grounded in an understanding of the lived experiences of those affected, and the real impact of cervical cancer upon all aspects of their lives. Throughout the process it was clear that this was a very disparate group of patients with very different situations and experiences. It was necessary to ensure that a representative record of their views was gathered to inform the Scoping Inquiry and provide a well-documented learning experience for the future direction of the screening programme.

A core principle of the World Health Organization's 'Health 2020' policy programme is 'the importance of participation and responsiveness, with the full engagement of people'.⁷ Participation involves people playing a central role as social agents, members of social networks, as collectives or as individual stakeholders, in decisions that affect their health and well-being.⁸ Engaging and enabling the public to take an active interest in their own health, making healthy choices and building healthy communities are essential to achieving public health goals; as well as contributing to socially sustainable health systems that reduce health inequities.⁹ These principles informed the Scoping Inquiry's mode of working.

⁷ Boyne T, Brown C. Reducing health inequities: perspectives for policy-makers and planners. Regional Office for Europe: WHO; 2017

⁸ Brown C, Harrison D, Ziglio E, Burns H. *Governance for health equity: taking forward the equity values and goals of Health 2020 in the WHO European Region*. Copenhagen: WHO Regional Office for Europe; 2013

⁹ Francés F, La Parra D, Martínez Román MA, Ortiz Barreda G, Vozmediano EB. *Toolkit on social participation*. Copenhagen: WHO Regional Office for Europe (in press)

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4.2 Communication

4.2.1 Overview

In order to make the Scoping Inquiry accessible to women or relatives of the deceased who wished to engage with the process, the following communication channels were made available:

- A website was created (www.scallyreview.ie) which provided an email and postal address by which the Scoping Inquiry could be contacted directly.
- A significant number of women and families affected contacted the Scoping Inquiry by telephone and arranged telephone conversations.
- Private group meetings were held for women and families affected in Dublin, Cork and Galway.

4.2.2 Telephone and Email

More than 150 women and families affected made contact directly with the Scoping Inquiry either via the dedicated email address or by telephone, with a further small number of women writing personal letters. All those who contacted the Scoping Inquiry received a personal response from me. For some, the ability to recount their story and views via email was sufficient. But a very large number wished to speak to me on the telephone. These were rarely, if ever, short conversations; and some were emotional and harrowing for the women concerned, or for the relatives, usually the husband, of the deceased.

I am grateful to the many women who decided to follow up on those email exchanges or telephone conversations by sending the Scoping Inquiry written statements of their experiences and views. Over twenty such statements were received. They were never less than forthright in their messages, never less than eloquent in their words and never less than heartfelt in their sentiments.

4.2.3 Personal Meetings

There were a number of very specific requests for face to face meetings with women and relatives of the deceased. All of these requests were responded to positively and they were amongst the most informative and emotional engagements.

4.2.4 Group Meetings

Given the geographical spread of those who had been impacted and in order to ensure as many as possible would be able to attend at least one meeting, group meetings were held in Dublin, Cork and Galway. The Scoping Inquiry has never been provided by the HSE with a list of the names or contact details of all of the women and families affected. This is entirely in keeping with my wishes as this would, in my view, be a breach of patient confidentiality. Rather, invitations to attend the group

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meetings were drafted by the Scoping Inquiry and issued by the HSE, who had contact details, to all the women and families affected.

Location of Meeting	Number of women and support people present
Dublin	130
Cork	60
Galway	67

Given the complex issues involved and the potential emotional impact of such a meeting on women and families affected, it was made explicit in the invitation that each invitee was welcome to be accompanied by a support person. It should be noted that there was a small number of women and families affected who did not wish to engage with the Scoping Inquiry in this way, if at all. Following the group meetings, many women and families affected have continued to engage with the Scoping Inquiry process by providing written statements of their experience and their cancer journey.

In the Interim Report, it was recommended that the Minister offer an immediate unconditional sum to each woman affected and to the next of kin of the deceased. This payment was recommended so as to ensure that no woman or next of kin encountered any financial barrier to participating and making their voices heard in the work of the Scoping Inquiry should they wish to do so. I am grateful to the Minister for having accepted this recommendation and I have heard from some of the women to whom this made a real difference.

In order to reassure invitees, it was made clear in the invitations that the group meetings were being held in private and would not be open to journalists or others to attend. A substantial effort was made to ensure that the meetings remained private via an advance registration process and a registration desk at the entrance to each meeting. Copies of the Terms of Reference of the Scoping Inquiry, the Progress Report and the First Report of the Scoping Inquiry (Information Provided to Women Receiving Screening and Treatment through CervicalCheck) were provided during the meetings.

For the women and families, the meetings were an opportunity to meet others who were in the same position as themselves and share their stories and experiences. Some women brought several family members or friends with them as support. Many of the women and families arriving at the meetings were visibly and entirely understandably nervous, anxious and tense. They were unsure what to expect and, in some cases, unsure of who else they might meet. Some were worried that they might meet people from their own community because their cancer diagnosis and treatment had not been shared beyond their immediate family circle. Some came in the hope and expectation that they might meet people facing the same serious concerns as themselves, for example fertility issues.

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I opened each meeting with a welcome and an introduction to the work of the Scoping Inquiry, including its remit, powers and progress to date. Each element of the process being followed was outlined. The women and families affected were then invited to make comments, ask questions, tell their personal stories and listen to each other. Each meeting lasted between two and three hours and, when meetings concluded, I stayed on to speak with any woman or family member who wished to do so individually. It was clear that some, having read of my appointment to lead the Scoping Inquiry, wanted the opportunity to see me in person.

It was important that the meetings allowed for frank and honest discussions. Some women and families chose to actively participate in the discussions whereas others chose to participate through listening. The privacy of the meetings facilitated the sharing of very personal information and were emotional for many. A small number of members of the Scoping Inquiry team attended each meeting and at some meetings were able to help answer specialised questions. The response at the end of each meeting, and in the days afterwards, was very warm and encouraging. It was clear that many who attended benefitted from the experience. Two people felt that the experience was so valuable to them that they actually attended all three meetings.

4.3 Stories, Experiences, Views, and Questions of the Women and Families Affected

“This has ruined many lives and has caused pain and suffering that can never be reversed and that needs to be recognised.”

The physical and emotional journeys that these women and their families have experienced are highly distinctive and it was absolutely essential to meet them and listen to their stories. The views and experiences discussed and noted during individual meetings and phone calls, the group meetings and individual written statements were collated and anonymised. The information has been used to obtain a fuller understanding of the context and complexity of individual situations and to identify the various issues that the women and families have faced. This process was key to recognising the real impact that this experience has had on women’s lives, and the ripple effect it has had on their partners, families and friends. During the meetings, some women mentioned that their relationships had broken down as a result of the treatment process. It has also left some women and families in financial difficulty.

It also must be noted that at each of the group gatherings, and in many of the other meetings and communications, warm tributes were paid to Vicky Phelan and her courage in challenging the system: in particular, her unwillingness to be silenced by a confidentiality agreement.

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4.4 Physical Impact on Women

From the stories and experiences recounted, it is clear that many women are still suffering with their cancer and having active clinical intervention. Others, despite having received effective treatment, continue to experience the life-changing effects of the illness and treatments such as hysterectomy, radiotherapy and chemotherapy. They recounted coming to terms with serious problems such as infertility, incontinence, lymphoedema, and sexual difficulties. During the meetings it was commented upon that it appeared there was no standard protocol for treatment from the point of initial diagnosis. From speaking with others in similar situations, women noted that they were receiving different treatments depending on their consultant and were concerned that the treatment they were receiving might be suboptimal.

“I had a missed smear and I am unable to have a family that I so desperately wanted. It hurts to hear that your life could have been different.”

4.5 Mental and Emotional Impact on Women and Families

“... my personal circumstances led to an extreme psychological reaction, I don't want this aspect to be overlooked in the inquiry.”

Cervical cancer is very much a physical disease where such remedies as medical science can provide often involve surgical procedures which can sometimes be extensive in nature. But, in addition, the treatment can also result in substantial psychological damage. The feeling was expressed that this aspect was often ignored by treating clinicians. Several women indicated that they have suffered, or continue to suffer with mental health issues as a result of their recent experiences. It was clear that for many women the trauma of disclosure and the intensity of media and political engagement with the CervicalCheck issues in the preceding weeks had exacerbated their psychological problems.

“The dread, panic and memories this brought up have been quite difficult to deal with over the past few weeks and I've been faced once again with taking time off work to manage my mental health.”

4.6 Self-Confidence

Many women spoke and wrote eloquently and sadly about how they have experienced a complete loss of confidence. There were three main components. Some women lost

- Confidence in themselves
- Confidence in the healthcare system
- Confidence in their treating clinicians

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In relation to the lack of confidence in their treating clinicians, at one of the meetings two women sat down beside each other at random and discovered that they were from the same town and had attended school together. Each of them had lost confidence in their treating clinician and, as they talked, came to realise that they were both considering switching to the other's treating clinician. They were amused by this, as was the rest of the meeting as they recounted it; but their story served powerfully to underline the seriousness of the problem.

4.7 Open Disclosure of Information Regarding the CervicalCheck Audit

The issues around non-disclosure of audit results by CervicalCheck will be dealt with at length in a later section of this report. But there was an overwhelming feeling arising from all of the meetings and communications that the issue of non-disclosure was felt very intensely, and often angrily, by many women. It wasn't just the non-disclosure, but the rushed nature of the disclosure that did take place after the publicity surrounding Vicky Phelan's court case that affected them adversely. The characterisation at the meetings of the manner in which women and families were told of their situation varied from unsatisfactory, to inappropriate, to damaging, hurtful and offensive.

There is one further important issue that was raised again and again by women at meetings, in emails and in telephone

"What is there in my notes that they don't want me to see?"

conversations, and this was about access to their medical records. Women expressed amazement and anger that it was so difficult for them to obtain a copy of their medical notes. I dealt with this issue to a limited extent in my first report.¹⁰ I am compelled to return to it because of the weight of concern that has been expressed to me. It is clear that entirely unreasonable delays in furnishing a copy of medical records could do nothing but engender suspicions of obfuscation and possible cover-up. There can be no good reason for the delays in giving women access to their clinical notes. It should not be necessary for women to feel that they have to engage solicitors in order to be provided with a full copy of their medical records in a timely fashion.

4.8 Accountability

There was a general sense across all three meetings and throughout the individual meetings, calls and emails that the women and families feel that they have been let down by the State. In the absence of clear and accessible information, it has all been too easy for some women and relatives to speculate that there have been conspiracies involving laboratory companies and that collusion has taken place to cover up scandalous failures. These adverse experiences created very clear challenges to the Scoping Inquiry in establishing its own credibility, commitment and ability to uncover what had been going wrong in CervicalCheck to the satisfaction of

¹⁰ Information Provided to Women Receiving Screening and Treatment through CervicalCheck. <http://scallyreview.ie/wp-content/uploads/2018/06/Scoping-Inquiry-First-Report.pdf>

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patients and their families. There were many calls for ‘somebody’ to be held accountable, with many expressing a lack of faith that such an outcome is probable.

4.9 Belief in Cancer Screening

Despite the negative experiences and significant impact that the CervicalCheck issues have had on these women and their families, there was vocal support for the concept of a national cervical screening programme. They do not want the programme abolished or damaged, rather they want to see it renewed and reinforced in ways in which they can have confidence and trust. They want a programme that will deliver patient-centred care and put the rights of women at the forefront of delivery.

“I can’t change the past but I can help shape the future for my sisters and nieces.”

4.10 Women’s Health

One key point that surfaced on several occasions was that most of the doctors involved in the disclosure (or non-disclosure) process were male. This, and the general way in which they felt they had been treated, led the women to develop concerns that the attitudes and lack of openness were accounted for by paternalism in the healthcare system. The point was made that many of the major controversies about maltreatment of patients or denial of reproductive rights in the Irish healthcare system have involved women being damaged.

“Why does it always happen to women?”

“I think there is a history of looking at women’s health services as being secondary.”

“Women and women’s rights are not taken seriously.”

“Paternalism is alive and well.”

There was a period when women’s health was taken very seriously. In 1997 the then Health Minister established The Women’s Health Council (WHC) with a remit to advise the Minister, and other Ministers, on all aspects of women’s health.¹¹ It had a comprehensive list of functions, quoted here in full and as they appeared in legislation.

- (a) *To advise the Minister for Health on all aspects of women’s health, either on its own initiative or at the request of the Minister and in particular on:*
 - *the implementation of the recommendations on women’s health contained in policy reports commissioned by the Minister for Health;*
 - *ensures to promote women’s health;*

¹¹ The Women’s Health Council (Establishment Order) 1997. S.I. No. 278/1997.

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- *action, based on research, required to plan and develop services to improve women's health;*
 - *methods of increasing co-ordination between public bodies at national and local level in the planning and provision of health services for women;*
 - *means of encouraging greater partnership between statutory and voluntary bodies in providing health services for women;*
 - *means by which the health services could assist the improvement of women's health in the developing world.*
- (b) *To assist the development of national and regional policies and strategies designed to increase health gain and social gain for women by:*
- *undertaking research on the health needs of women in Ireland;*
 - *identifying and promoting good practice in the provision of health services for women;*
 - *providing information and advice based on research findings to those involved in the development and/or implementation of policies and services pertaining to the health and well being of women;*
 - *liaising with statutory, voluntary and professional bodies involved in the development and/or implementation of national and regional policies which have as their object health gain or social gain for women.*
- (c) *To develop expertise on women's health within the health services.*
- (d) *To liaise with international bodies which have functions similar to the functions of the Council.*

During the course of its existence, the WHC undertook an extensive and impressive body of work and produced authoritative reports on a wide range of issues pertaining to women's health, including:

- *Women's mental health: promoting a gendered approach to policy and service provision;*
- *Women's health in Ireland: meeting international standards;*
- *Women and cardiovascular health: a position paper of The Women's Health Council;*
- *Women, disadvantage and health: a position paper of The Women's Health Council;*
- *A guide to creating gender-sensitive health services.*

Despite an announcement in 2003 that it was to be 'integrated' into the then Department of Health and Children or the HSE, the WHC survived until 2008, when the Minister for Health and Children announced a major programme of agency rationalisation in the health sector that included the WHC being integrated into the

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Department of Health and Children. It is probably more accurate to refer to it as having been a 'disappearance' rather than a 'merger'.

4.11 Analysis

I cannot but agree with those patients and their families who told me that more and different attention needs to be paid to women's health issues. It would be presumptuous to recommend the reconstitution of the Women's Health Council but I am convinced that there does need to be an exploration of how women's health issues can be given more structured and consistent attention.

4.12 Recommendation

- 2) The Minister for Health should give consideration to how women's health issues can be given more consistent, expert and committed attention within the health system and the Department of Health.
- 3) The Department of Health should examine the current arrangements for patients to have access to their hospital medical records so that such access can be achieved in a timely and respectful way.

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5 CervicalCheck – Organisation and Governance

5.1 Overview

CervicalCheck provides free cervical screening to women in Ireland aged 25 to 60. Cervical screening is provided for women who are asymptomatic and presumed to be well, with the aim of preventing the development of cervical cancer. The administrative offices of the programme are located in Limerick. The CervicalCheck programme is managed by the National Screening Service (NSS), a part of the Health Service Executive (HSE), with funding provided by the Department of Health through the HSE vote allocation.

The stated goal of CervicalCheck is to reduce the incidence of, and mortality from, cervical cancer among women in Ireland. This goal is to be achieved through the screening of as many women as possible within the target population in order to detect pre-cancerous cervical cell changes and to treat high-grade pre-cancerous lesions.

It is worth stating at the very outset the very substantial contribution that CervicalCheck staff have made to women's health over the ten years of the programme. Equally important and worthy of recognition is the way in which they have striven to keep the screening service operating in the middle of the controversy that has engulfed it in recent months.

5.2 How the CervicalCheck Programme is Delivered

The delivery of the CervicalCheck programme is reliant upon a large number of contracted service providers. The most significant of these are for test-taking and cytology. Additionally, CervicalCheck has memoranda of understanding with acute hospitals for the provision of colposcopy services.

The NSS contracts with General Practitioners (GPs) and clinics in the primary care setting for the taking of cervical tests. Test-taking is undertaken by GPs and practice nurses. Contracts are arranged with the GPs and clinics and fees per service are agreed within the contract. CervicalCheck organises training programmes for these test-takers.

Cytology services for the purpose of testing the samples are provided by two private sector laboratory companies and one public voluntary hospital; the procurement and contractual arrangements associated with these providers are discussed in detail in Sections 6 and 7 of this report.

The results from the laboratories in respect of the tests which they have analysed are then communicated back to the women and their test-taker by CervicalCheck. Depending on the result, a woman may be advised to have a repeat test in three

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months (for unsatisfactory/inadequate tests), three years, or five years. In cases where an abnormality is suspected, a woman will be referred to colposcopy.

In the case of such referrals, the woman will attend a colposcopy clinic located within an acute hospital that has an agreement with CervicalCheck. She will first have a colposcopy, which is a detailed examination of the cervix, using a type of microscope called a colposcope. This may include a biopsy of the cells of the cervix. The woman will then be treated appropriately depending upon the results of the colposcopy and/or biopsy. Diagnosis will occur at this stage. A woman will then be recommended for treatment, a return to routine screening, or a test in one year.

5.3 Costs of the CervicalCheck Programme

The total cost of the CervicalCheck programme in 2018 is expected to be just under €23.9m. In the table below, the net expenditure budget for the CervicalCheck programme for 2018 is presented. The non-pay budget includes:

- GP and other Smertaker payments - €12m;
- Laboratory costs - €6.8m (Cytology and HPV);
- Consumables - €2.3m.

	Budget 2018 (€)
Pay	1,173,991
Non pay	22,708,784
Total expenditure	23,882,775
Income	-231
Net expenditure	23,882,544

Table 5.3-a: CervicalCheck Budget 2018

It should be noted that funding of €7.45m, not included above, is provided by the CervicalCheck programme to fund colposcopy services in 15 acute hospitals. This expenditure was included in the 2018 Acute Hospitals budget.

By comparison, the 2017 budget for CervicalCheck was €24.3m – the 2018 budget saw a reduction of around 1.6%. The total budget for all NSS programmes in 2018 is €77.8m, which includes an allocation of €18.2m to hospitals.

5.4 History and Background – the Status of CervicalCheck

CervicalCheck evolved from the Irish Cervical Screening Programme (ICSP), which ran a pilot version from October 2000 in the then Mid-Western Health Board area (Limerick, Clare, and North Tipperary). The ICSP was under the aegis of the Mid-Western Health Board, which was subsumed within the HSE in January 2005. The National Cancer Forum's *A Strategy for Cancer Control in Ireland* in 2006 recommended amalgamating the ICSP with BreastCheck into one agency.

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On 1st January 2007, a Statutory Instrument set up the National Cancer Screening Service (NCSS), governed by the National Cancer Screening Service Board (NCSSB). The NCSSB brought cervical screening, under the new name CervicalCheck, and BreastCheck together and reported directly to the Minister for Health and Children. It still maintained a close relationship with the HSE but was no longer under its direct governance from 1st January 2007.

It would appear that this structure was designed to be short-term, as the NCSS was intended, in due course, to become part of the National Cancer Control Programme (NCCP), as noted in documentation such as the BreastCheck programme report 2008-2009.¹²

The NCSS was a State Body until 1 April 2010, when it was moved back into the HSE under the National Cancer Control Programme (NCCP), which was part of the HSE. At that point, the Board (NCSSB) was dissolved. This move was prompted by a programme of rationalisation of health agencies announced at the end of 2008. CervicalCheck continued its work as a part of the NCSS, which operated as a business unit within the NCCP.

On 1st January 2014, the NCSS was moved out of the NCCP and into the HSE National Directorate of Health and Wellbeing as part of the HSE organisational transformation programme. In the same year, the NCSS was renamed the National Screening Service (NSS) due to the introduction of the Diabetic Retinopathy Programme.

The NSS was moved from the National Directorate of Health and Wellbeing back to the NCCP Directorate within the HSE in early 2018.

The basic timeline below illustrates the key strategic dates for CervicalCheck in relation to its status:

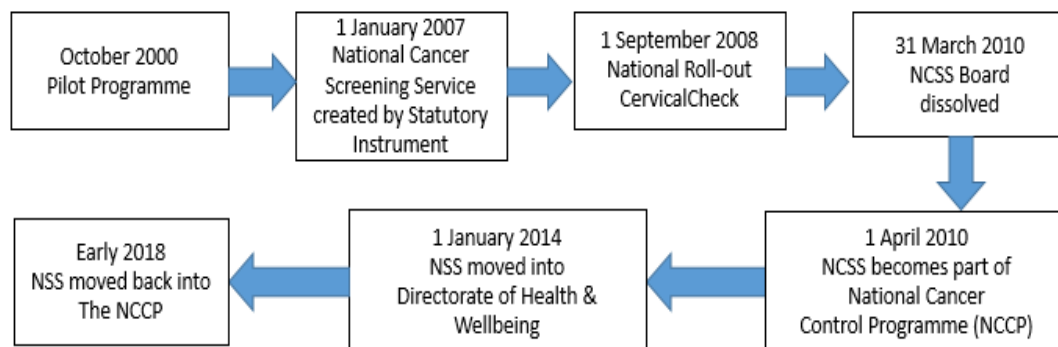


Figure 5.4-a: Timeline of CervicalCheck

¹² BreastCheck - Programme Report 2008-2009. p14.

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5.5 Management and Internal Governance within CervicalCheck

5.5.1 Current Organisational Structure of CervicalCheck

The current organisational structure of CervicalCheck combines the delivery of certain core activities through internal programme functions alongside the contracted services from external service providers. This organisational model is presented in Figure 5.5-a below.

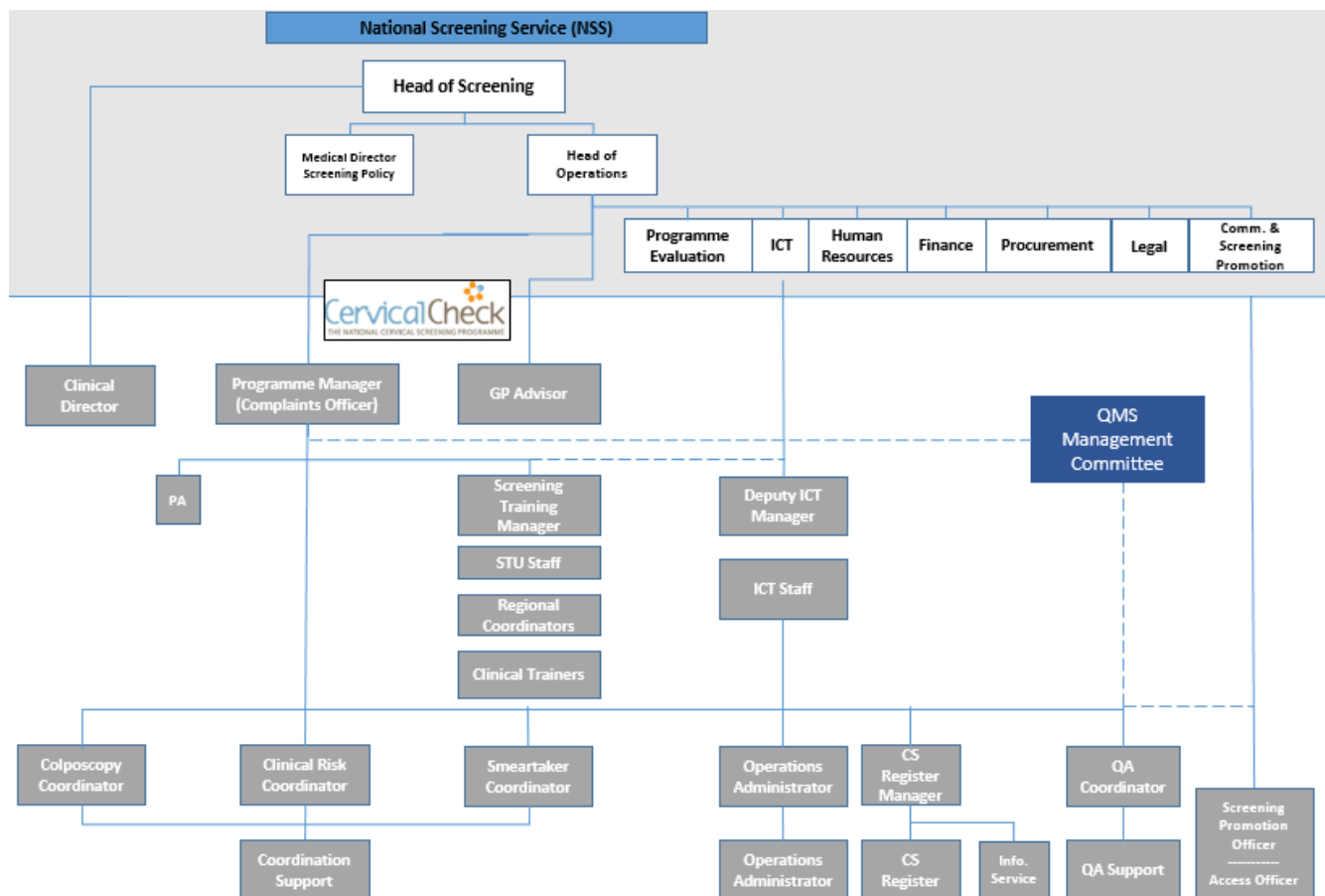


Figure 5.5-a: Current CervicalCheck Organisational Chart

The programme functions of CervicalCheck include:

- Client Communications – this function includes information provision and enquiry handling through the Information Service (Freephone, Freepost, email, online ‘Contact Us’), as well as contact and engagement with clients. This contact and engagement can include advertising, screening promotion, informational and promotional materials, website and online facilities, and responding to feedback from women.
- The Access function is implied in all aspects of programme operation: women are facilitated to participate in the programme if they choose to do so. This includes a dedicated point of engagement for women who encounter difficulties

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in accessing the programme and may require special arrangements in order to do so.

- The Cervical Screening Register function manages the records of women on the Cervical Screening Register (CSR), including demographic details of eligible women, their screening history, and recommended management. It generates letters to women for invitation (call) and re-call, following screening test results, and for failsafe.¹³ This function also processes information received from women, doctors, nurses and associated staff, laboratories and colposcopy clinics to update the screening records of women.
- Key service providers include GPs and GP practices, and clinics in both primary care and other settings, laboratories (cytology, HPV testing, histology), and colposcopy clinics.
- Screening Training, Clinical Risk Coordination, Smeartaker Coordination, and Colposcopy Coordination integrate services for patients, while monitoring activity and performance against quality assurance guidelines in line with the terms of contracts.
- Operations Administration manages the registration of doctors and nurses for cervical screening, the supply of screening consumables, communication to service providers, processing of payments, purchasing of supplies, and administrative support for other functions.
- The ICT (information and communications technology) function provides the secure operation and ongoing enhancement of the computerised CSR database at the core of programme operations, as well as the linkages between it and external systems. It manages the ICT infrastructure and applications that support programme functions in both planning and monitoring service delivery. These include document management systems, reporting tools, quality and risk management systems, and shared storage for intra-team collaborations. ICT support resources are shared across the NSS.
- The Quality function within CervicalCheck implements and manages the quality management system (accredited to ISO 9001) for the control of documents, procedures and work instructions, the quality checks on services provision, the recording of incidents and their follow-up. Quality ensures that monitoring and measurements are used as the input to continuous improvement initiatives.

5.5.2 Management and Reporting within CervicalCheck

As Figure 5.5-a (above) shows, the CervicalCheck programme does not have a single manager who is accountable for the service, but instead has two senior positions – a Clinical Director who reports to the Head of Screening in the NSS, and a Programme Manager who reports to the NSS Head of Operations (who in turn reports to the Head of Screening). It should be noted that the senior NSS positions

¹³

Failsafe is a request that abnormal results are communicated to the woman by their treating clinician as well as directly by the programme.

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also have management responsibility for the other three screening programmes run by the NSS – BreastCheck, BowelScreen and the Diabetic Retinopathy programme.

This arrangement, with two senior positions in CervicalCheck reporting to different individuals within the NSS, has been in place for much of the existence of CervicalCheck. However, up to 2010, the position of Head of Cervical Screening existed within the structure, and provided a single channel of leadership and accountability for the programme. However, the post-holder retired in December 2010 and there was no replacement. Instead, there was an organisational restructuring: the Programme Manager (a pre-existing post) became the effective administrative and operational head of cervical screening, with clinical leadership coming from the Clinical Director. The position of Clinical Director, which is currently vacant, was most recently filled on a part-time basis by a Consultant in Obstetrics and Gynaecology based in one of the Dublin maternity hospitals.

Since 2010, therefore, CervicalCheck has not had a single, accountable senior person responsible for the delivery of the programme on a full-time basis.

5.5.3 *Role Clarity*

Based on the information provided to the Scoping Inquiry, and meetings with a significant proportion of CervicalCheck staff, it would appear that there is an issue with the provision of job descriptions. Many staff, including those in senior management positions, told the Scoping Inquiry that their positions often lacked formal job descriptions. One staff member only saw their job description when they left their role and saw an advertisement for their replacement. At a meeting with CervicalCheck staff in Limerick in August 2018, the Scoping Inquiry asked how many people out of the 20 or so in attendance had a current job description which matched their role – only one person, a new recruit, was able to state that this was the case.

Even when there are job descriptions provided, it is likely that the job description does not accurately reflect the role as it is currently constituted. For instance, one staff member reported that they had an additional major job responsibility not referred to in their contract, meaning that their job description was inaccurate, as it only included one of their roles. Additionally, the Scoping Inquiry was advised that a job within CervicalCheck was advertised with a role summary prepared without input from anyone in the programme, including a staff member with a similar role who could have provided helpful feedback. This job was not filled.

5.5.4 *Recruitment Issues*

The Scoping Inquiry found some evidence that appropriate procedures were not followed when staff were being appointed to positions in CervicalCheck and the wider NSS.

In recent years, CervicalCheck has experienced difficulty in attracting and recruiting new staff members. In 2016, a member of the senior management team was

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seconded outside of the NSS. There were two attempts to recruit a replacement that were ultimately unsuccessful. There were no further attempts to replace that member of the senior management team. The NSS tried in 2017 to recruit a new member of the executive management team; again, without success. There is no indication in the information available to the Scoping Inquiry of further action on recruiting to these positions by either the NSS management or HSE leadership.

Staff recounted how the Irish bank guarantee occurred three days after CervicalCheck was launched nationally in September 2008. As the financial crisis contributed to an economic recession, public sector programmes and organisations saw a reduction in the level of resources afforded to them, with CervicalCheck no different. As its budget was reduced, CervicalCheck struggled to adequately replace departing staff.

5.5.5 Staff Performance Appraisals

There is an absence of regular performance appraisals for staff within CervicalCheck. Staff members reported to the Scoping Inquiry that performance appraisals were rarely carried out, and a belief that this was due to a lack of standardised practice. The lack of performance appraisals further suggests a lack of effective oversight within the organisation. Without performance appraisals it is difficult, if not impossible, to determine if staff in an organisation are being utilised effectively; and whether their training and continuing professional development are keeping pace with the needs of the organisation.

5.5.6 CervicalCheck Committees and Groups

Analysis of documentation pertaining to CervicalCheck over the course of its history shows that it had many groups and sub-groups established at various times to deal with specific issues. Only a few have met regularly since its inception, including:

- CervicalCheck Executive Management Team (CEMT);
- CervicalCheck Management Team;
- CervicalCheck Quality Assurance (QA) Committee;
- CervicalCheck Operations Group.

The CEMT has included the Director of the NSS, the Head of Cervical Screening (up to late 2010), the NSS Head of Operations, the CervicalCheck Clinical Director, the Programme Manager, and other managers as required. The function of the CEMT is to formulate policy on key programme matters, and to develop and monitor the service plan.

The Management Team includes the heads of operational sections of CervicalCheck. The meetings are more operational in nature and focus on particular areas of activity rather than broader organisational issues.

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The Quality Assurance Committee was established to review international standards, recommend best practice, and monitor and evaluate achievement of recommended standards, while monitoring and supporting adherence to these by service providers. Some members of this Committee are external to the NSS and many are medical consultants. Representatives of organisations such as the Irish Society for Colposcopy and Cervical Pathology (ISCCP) are also present as members of this Committee. Section 5.5.7 below deals with this Committee in greater detail.

The Operations Group was originally intended to coordinate activities in relation to the national roll-out of the CervicalCheck programme, but remained in operation long after the national roll-out. It continues to meet and discuss operational issues, which appear to be very similar to the ones discussed in Management Team meetings.

5.5.7 CervicalCheck Quality Assurance Committee

From its earliest days, CervicalCheck had a Quality Assurance (QA) Committee which met quarterly. In early 2014, it was reconstituted following changes in the structure surrounding the screening services and it only met twice in that year. Following its reconstitution, under the same Chair, the Committee continued as before but with slightly more external input. The same person chairs the QA Committees for three of the four screening programmes operating under the NSS.

The QA Committee had a number of subgroups that concentrated on the development of standards for key functions in the screening process, such as cytopathology, primary care, histopathology, colposcopy and administration.

From QA Committee minutes, it is clear that it received reports on some policy and management issues as well as more narrowly defined QA issues. However, although the QA Committee was made aware of the existence of an audit of screening cases by CervicalCheck in 2009, it was never party to discussions about the operation of that process. Based on the papers supplied to the Scoping Inquiry, it appears that the QA Committee was unaware of and did not see any of the seven iterations of the audit process documentation. Given the content of those papers relating to the QA Committee, it appears that the quality assurance of those screening audit process documents would fall squarely within its remit.

The Committee was aware of QA visits to laboratories (see Section 6.9). For example, in November 2014, the Committee discussed visits to three laboratories that took place in February and March of that year. The auditors were thanked at the Committee meeting for their efforts and commended on their reports. The Committee and the auditors were unaware that there might have been laboratory sites involved in CervicalCheck work other than those specified in the contracts.

There are learning points that may arise from some aspects of governance of the QA Committee. Firstly, the Chair appointment, which is remunerated, has no fixed time period associated with it and the current incumbent has been in position since the inception of CervicalCheck. (The Scoping Inquiry makes no criticism of the individual

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concerned, merely the indefinite nature of the appointment, where a fixed-term arrangement would represent good practice.) Secondly, some of the members of the QA Committee are described in documentation as ‘representatives’ of their respective professional bodies. Neither of these aspects of its functioning are satisfactory.

5.5.8 CervicalCheck and the Screening Audit Process

The screening audit process will be discussed in detail later in this report in Section 8 but is also worthwhile to outline some aspects of the process in more detail in this section.

As noted in above, the first documented discussion in respect of the screening audit process was in the minutes of the QA Committee meeting of January 2009, which stated that the then-head of CervicalCheck presented a draft flowchart for cancer audit to the meeting. The minutes of the March 2009 meeting note that the cancer audit process was presented and agreed. Later in the same meeting, the development of standards, guidelines, and quality assurance protocols for the cancer audit were touched upon. In May 2009, according to the minutes of the meeting, the QA Committee was informed that the cancer audit process had been developed and could now be implemented. According to the minutes, the Committee ‘agreed that implementation is a management function and therefore this action item can be closed for the QA Committee’.

Key aspects of the cancer audit process that took place from 2010 include the following:

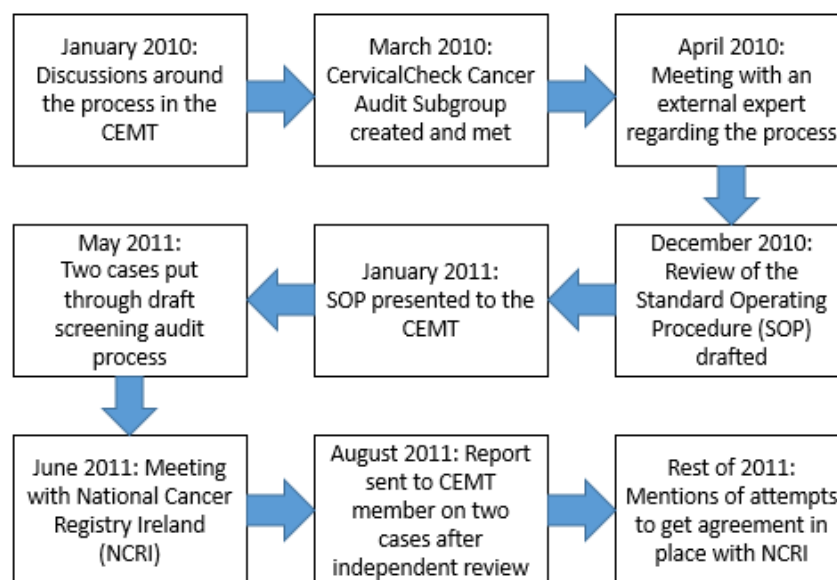


Figure 5.5-b: Timeline of Beginning of Screening Audit Process in CervicalCheck

In 2012, the Standard Operating Procedure (SOP) was reviewed and revised. This was referred to as ‘Clinical audit process for incident cases of invasive cervical

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cancer'. Minutes of the CEMT note that legal advice was obtained in relation to the process. Ties with the HSE Quality and Patient Safety Directorate were established in early 2013 in cases where it would be necessary to notify the Quality and Patient Safety Directorate and the hospital Risk Manager. The cancer audit process continued into 2013 and 2014, with regular monitoring and refinement; updates were discussed in meetings of the CEMT.

In August 2015, an external cytopathologist met with two members of the CEMT to discuss the external cytology reviews for the cancer audit process carried out to date. A presentation was given to the CEMT regarding the cancer audit process in September 2015.

5.5.9 *Proposed Establishment of a Governance Group within NSS/CervicalCheck*

In 2014 there were some signs that governance within the screening service might be an issue. In February 2014, it was noted at a meeting of the CEMT that the HSE National Director, Health and Wellbeing (to whom CervicalCheck now reported), had requested that a governance group be created for screening (i.e. all programmes, including CervicalCheck). However, at the following meeting, with only three members of the CEMT in attendance, the minutes noted that it was agreed, in relation to the screening governance group, that 'There has been no further consideration of this. It can be removed as an action, and can be revisited if necessary in the future'.

The Scoping Inquiry has no documentary evidence to suggest any further action and has not had the opportunity to make further enquiry of all the individuals who might have information in this regard.

5.6 External Governance of CervicalCheck

5.6.1 *Overview*

An earlier section of this report considered governance issues within CervicalCheck as an organisation. This section examines briefly the governance and oversight of CervicalCheck within the wider structures of the HSE and Department of Health.

5.6.2 *CervicalCheck within the HSE Governance System*

The positioning and operation of the NSS within the HSE, and within the Health and Wellbeing Directorate, has not been without difficulty. The view was expressed to the Scoping Inquiry by some working within NSS, that screening was downgraded after being absorbed into the HSE and that they felt they had little influence within the HSE as a whole. It is clear that relegating the screening services from being a separate public body dedicated to cancer screening, to being a small component lower down the organisational structures in a body as large and complex as the HSE was significant for the staff and governance.

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5.6.3 The National Screening Service and the Health and Wellbeing Directorate

CervicalCheck is one of four screening services that together comprise the National Screening Service (NSS). The organisation dropped the word 'Cancer' from its title after the initiation of a diabetic retina screening programme. The service has, until recent months, been part of the Health and Wellbeing Directorate. Its positioning there was regarded as appropriate, given that screening is a public health programme and therefore it should sit within the broader prevention sphere. As noted above, the National Screening Service had a Head of Screening who reported to the Health and Wellbeing National Director, and a Head of Operations, to whom the CervicalCheck Programme Director reports. Both the Head of Screening and Head of Operations of the NSS attended the CervicalCheck Executive Management Team meetings.

5.6.4 External Report on NSS

It appears that there was an appreciation at the top of the HSE that all was not well. In early 2017 a report was published by an external consultancy company that been engaged by the Director General of the HSE to review the 'functionality and governance' of the NSS.¹⁴ The authors of the report approached the task by, in their own words, focusing on 'taking the temperature' in relation to governance and functionality within the NSS. This qualitative review was based mainly on interviews with NSS staff.

Amongst other findings the report noted that:

...there continues to be a somewhat negative relationship and clear disconnect described by the programs between themselves and the HSE chain of command. Issues of isolation, suspicion, lack of trust or support and poor or non-existent communication were cited.

The authors of the report also noted that there was 'relatively low integration' across the four programmes, with divided opinions as to whether they were four separate organisations or one collective enterprise.

The report made a series of eight recommendations. These included:

- Enhancement of the NSS leadership structure,
- Development of a strategic plan,
- Better cross programme working,
- Externalising the QA process,
- Increasing lay involvement;
- Transferring the NSS to operational health service delivery.

¹⁴ Prospectus. High level review of the overall functionality and governance of the HSE National Screening Service. 2017.

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The Scoping Inquiry did not perceive, from the information available to it, any visible signs of these recommendations being implemented except, arguably, the move of NSS into the NCCP in early 2018.

5.6.5 Risk

A key weakness in the governance structures within the HSE in relation to CervicalCheck and the NSS is how risks are identified, communicated, and managed, and in particular the processes by which serious risks can be communicated to the appropriate senior HSE management levels, and, if necessary, to the Department of Health.

In its 2010 Annual Report the HSE listed four initiatives that it stated could improve the safety and quality of health services in Ireland. One of these was:

A system of risk registers has been established. Risk registers allow an organisation, or unit within an organisation, to identify risks (including risks to patients) and to strengthen its efforts to reduce these risks.¹⁵

A risk assessment conducted during spring 2012 placed ‘false negative’ screening outcomes at 18th on a list of the 28 most severe risks to CervicalCheck. The programme placed emphasis on potential risk events which could prevent the programme from achieving its performance objectives (such as the screening attendance rate dropping below an acceptable threshold), but the risk of women being harmed by systemic failures does not appear, from the information that the Scoping Inquiry has seen, to have been given due consideration.

The HSE considers risk a ‘line management issue’, which means that it is assumed that risks and issues are managed locally, until they are communicated to appropriate individuals; perhaps with a request for resources to deal with them.

Prior to the dissolution of the HSE Board in July 2013 (discussed below), the HSE had a Risk Committee with considerable potential influence, as it had both an independent chair reporting to the Board and four members of the main Board of the HSE. Even though the HSE Board structure disappeared in July 2013, the Risk Committee had already met on four occasions.

A Risk Committee with an independent chair, comprising four Board members, one independent member and three members of HSE senior management was in place until the dissolution of the Board in July 2013. This Committee met on four occasions in 2013. The Chairman of the Risk Committee was not a member of the HSE Board but reported to the Board on all significant issues considered by the Committee.¹⁶

¹⁵ HSE. Annual Report and Financial Statements 2010. p19.

¹⁶ HSE. Annual Report and Financial Statements 2013. p79.

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After the dissolution of the Board, and the introduction of the Directorate model (considered further in the following section) things changed.

Following the enactment of the Health Service Executive (Governance) Act, 2013, a Risk Committee was established, reporting to the Directorate. This Risk Committee has an independent chair and comprises a Director and four external members. The Risk Committee of the Directorate met on one occasion in 2013.

The abolition of the HSE Board meant that its reconstituted Risk Committee no longer had a Board to which to report, or the external governance asset that the Board's membership from outside the organisation represented. Although the HSE's reconvened Risk Committee continued to include external membership it lacked the influence that it previously possessed. As a Chair of the Committee told the Scoping Inquiry, 'We were tolerated rather than embraced'. The Committee was perceived to be particularly concerned with health and safety issues and non-healthcare risks, with clinical risk issues and patient safety being of lesser concern.

In 2017, a new approach to risk reporting in the HSE was adopted, where pre-defined categories of risk were identified (harm being one of these). Services were offered a fortnightly opportunity to notify risks to the divisional (Health and Wellbeing) risk register. The NSS did not at any stage opt to notify risks to this divisional register. According to documentation supplied to the Scoping Inquiry, it appears that the NSS was confident that risks were being adequately mitigated at local level. HSE management does not appear to have ensured that appropriate and consistent risk management processes were in place within the NSS, again suggesting a pattern of not following through on key governance processes.

The reporting of risk within the NSS did mention some of the issues surrounding screening. For example, in the NSS Risk Register report for October 2017 there were five risks described. One of these, entered on the register in March 2017 and categorised correctly as 'Harm to a Person', read:

Screening tests are a balance of sensitivity and specificity and therefore include both false negative and false positive results which could affect the screening outcome and treatment of a person who may or who may not have a disease.

This is a statement of fact, but would appear to the Scoping Inquiry to be inadequate as a description of risk. Under the list of 'Existing Controls' for that risk is a direct reference to the CervicalCheck audit:

Clinical Audit process established and embedded in CervicalCheck by December 2017.

This is also difficult to understand, as the audit process commenced many years previously.

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5.6.6 Governance of the HSE Itself

As noted in the paragraph above, changes to the overall governance of the HSE itself had a significant impact. In March 2012 the Board of the HSE, which had consisted of external, non-executive Chair and Board members, was removed and replaced by a Board consisting of civil servants and HSE officials. This change from the accepted good practice of having independent Board members in an oversight role, and involved in a committee structure beneath the Board, was a major move away from the established norms of good governance of public bodies. It is difficult to see who, under this configuration, was representing the patient and public interest.

In the case of civil servants appointed as Board members, it raises the question of whether they are acting in their civil service capacity, supporting Ministers to carry out Government policy, or are there to administer a major public body in the interests of the public it serves. This was further compounded by senior civil servants at times fulfilling two roles, one in a senior executive position in the Department of Health and the other within the top-level governance structure of the HSE.

In 2013, legislation changed the nature of the governance of the HSE entirely, replacing the Board structure with a Directorate consisting of a Director General and no fewer than two, and no more than eight, Directors all of whom were HSE staff.¹⁷ The Director General and Directors were all effectively appointed to the Directorate by the Minister for Health. It is recognised that this was a step along the intended path of abolition of the HSE, but the net effect was to remove external, independent input into the running of the HSE at its highest level.

The 2018 proposals to restore a Board system to the HSE reflects the continued existence of the organisation, rather than its planned abolition, and also represents an opportunity to reflect the patient and public interest at the highest level of the country's health service.

5.6.7 Department of Health Oversight

Since the establishment of the NCSS in 2007, the Department has had varying levels of oversight. From its establishment until 2010, the NCSS was a State agency under the direct oversight of the Department. Once screening became part of the HSE, the level of direct oversight was reduced, but the Department maintained an ongoing working relationship with the screening service.

From 2007 to 2010, the level of Departmental oversight was driven by the practice of normal Departmental oversight of a State body. This included regular engagement with the CEO and management team members. Following a governance issue regarding the Board of the NCSS not receiving the approval of the Minister as required by the establishment order (as set out in the Statutory Instrument), the

¹⁷

Health Service Executive (Governance) Act 2013. <http://www.irishstatutebook.ie/eli/2013/act/23/enacted/en/pdf>

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Department established a monthly meeting with NCSS management. These meetings focused on financial issues and the roll-out of the service.

These meetings were not intended to discuss operational matters. The Department was informed of all significant issues, including the decision to tender for laboratory services in both 2008 and 2010. The Department was also informed of the outcome of the procurement process.

Around this time, concerns were raised within the Department regarding the role and approach of the NCSS. These concerns ranged from a concern that the NCSS may have been inappropriately driving policy decisions, to the Board arguably overstepping its remit and entering into a lease agreement without the prior approval of the Minister.

Following absorption into the HSE in 2010, the NCSS continued to meet with the Department on a monthly basis as part of the NCCP. These meetings, which were with the Cancer and Blood Policy Unit, focused on the NCCP as a whole and the NCSS was only one element in the discussions. Much of the discussion of cervical screening was in relation to the level of uptake.

It should be noted that this regular and continuing engagement between senior Department of Health officials and the relevant officers of the HSE was unusual, but is seen to represent good practice in terms of working together to identify and solve issues. It would therefore have been an entirely suitable venue for the screening service to have initiated a fully informed discussion about the audit. That opportunity was missed.

Following the now-NSS move to the Health and Wellbeing Directorate within the HSE, the NSS continued to attend the monthly meetings with the Department and NCCP. It was at one of these meetings in March 2016 that the screening audit process was first mentioned. The cancer audit was brought up under 'any other business'. Subsequent to this meeting, the first of the briefing notes relating to the audit process was provided to the Department.¹⁸

In the period after the March 2016 meeting, the audit was referenced at a number of standing departmental meetings with the NCCP, the NSS, and the Health and Wellbeing Directorate. The meeting notes on the issue record that the communication process was ongoing. There were three further briefing notes provided to the Department during 2016. The final mention of the audit in 2016 was at the September meeting with the NSS and the NCCP. The Department welcomed the audit process as part of the learning and improvement of the service, but was not made aware of any concerns over deficiencies in the process.

¹⁸ This documentation is available at https://health.gov.ie/wp-content/uploads/2018/05/180515_CervicalCheck_Departmental-2016-Documents.pdf

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The Department was not informed of any further issues with the audit until Friday 6th April 2018. This communication was in the context of informing the Department of a case that was scheduled for hearing on 19th April 2018. The case was due to commence mediation on the following Monday. This information prompted the Department to request further information from the NSS and subsequently brief the Minister.

Based on the documents supplied by the Department, there is no indication that the Department was aware of the scale and potential impact of the issues in respect of the handling of disclosure in relation to the CervicalCheck audit process until April 2018.

It is apparent to the Scoping Inquiry that there is a serious gap in the arrangements for the proper governance of screening in general. There is a need for an expert body to support the Department of Health in the development of policy on both new and existing screening programmes. Such a body would reassure both Ministers and the public that Ireland's screening programmes were evidence-based and that the policies being implemented were appropriate.

5.6.8 Ministerial Oversight

The regular engagement by the Minister with the HSE is at Director General level. This oversight is supported by Department Officials engaging with the various directors. When necessary, issues are brought to the attention of the Minister through both of these channels.

The Scoping Inquiry has not seen any evidence that any issues with regard to CervicalCheck were brought to the attention of the Minister prior to April 2018, when the Department became aware for the first time that a case was scheduled for hearing on the 19th April.

As noted previously, Department officials met regularly with the NCCP and the NSS. There was also engagement by officials in relation to parliamentary questions and ministerial representations. There were no indications in 2016 that the screening audit should be brought to the attention of the Minister. One draft set of meeting minutes from June 2016 did reference that briefing documents to be provided by CervicalCheck 'can be used to brief the Minister', but this reference does not appear in the final approved minutes. The Scoping Inquiry has seen no evidence to suggest that such a briefing for the Minister was ever prepared or took place.

5.7 Communication between CervicalCheck, the HSE, and the Department

As outlined above, on the basis of the information available to the Scoping Inquiry, there appears to have been a lack of clear governance and adequate reporting lines between CervicalCheck, the NSS, and the HSE management structures. This confusion complicated the reporting of issues and risks. The organisational distance of CervicalCheck from those responsible for the ultimate oversight of the programme

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also impacted on the level of communication. It appears that the practice of CervicalCheck was to keep matters within the programme unless it was necessary to communicate with others.

An example illustrating the communications between CervicalCheck and those to whom it reported concerns the briefing notes mentioned above, prepared in 2016 regarding the screening audit process.

After the commencement of the disclosure exercise in February 2016 CervicalCheck prepared a series of briefing notes, variously titled, but all referring to the screening audit and the disclosure of its findings. The purpose was to brief senior officials in the HSE and in the Department of Health about the screening programme, the retrospective audit of the cases of women known to CervicalCheck who had developed cervical cancer and the progress of the disclosure process.

The six notes were dated:

- February 2016
- March 2016
- April 2016
- July 2016 (1)
- July 2016 (2)
- October 2016

The second of the July notes was longer, contained more detail, and was the one used for onward transmission to the Department. The notes, in various amounts of detail, outline the nature and limitations of the cervical screening programme, the scope and size of the audit process and the risks associated with following the process of open disclosure of the results of the audit.

The note from March 2016 states:

At this time the process is approaching the stage of communicating individual case reports arising from the clinical audit with the clinicians looking after individual women diagnosed with cervical cancer.

This was corrected in the July 2016 notes to accurately state that the communication to the treating clinicians had started in February.

In February 2016, the programme commenced the formal step of communicating cytology review findings arising from the clinical audit to the treating clinicians

There is a phrase used in the March 2016 note which does, in a very minor way, indicate that whilst the results of the individual review of slides will be provided to the clinicians, the results may not necessarily be onwardly disclosed to the women.

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...the risk of an individual reacting to the content if/when shared by their attending clinician.

The March 2016 note also strikes a reassuring tone in relation to the overall quality of the programme.

Most importantly during the conduct of the clinical audit to date no systematic quality problem of concern has been identified.

The notes mention the legal objections raised by one of the laboratory companies to the disclosure to women of the results of the review of slides. But it is clear that CervicalCheck, with legal advice, were maintaining that the principle of disclosure, in keeping with the HSE policy, was correct. As noted in the July briefing notes, CervicalCheck advised that the matter was resolved satisfactorily with the laboratory concerned. Although it temporarily halted the dispatch of letters to treating clinicians, it appears to the Scoping Inquiry to have had no other significant effect.

Overall, it appears to the Scoping Inquiry that the tone of the notes, while pointing out the nature of the audit and the risks associated with disclosure, are reassuring, in that they seem, to the Scoping Inquiry, to convey the picture of a screening programme which is dealing with difficult issues and managing them appropriately. The notes do not propose any matters for decision or request action from other parties.

The notes are, as they are titled, 'briefing notes', and clearly designed to inform rather than seek agreement or action on behalf of other parties. It was, in the view of the Scoping Inquiry, entirely appropriate to share them with officials in the Department with whom they had regular and constructive contact via a series of meetings. According to the information available to the Scoping Inquiry, the Department was in receipt of four of the notes, starting with the March 2016 version, and the Director General of the HSE was in receipt of three of the notes.

The subsequent issues confronting CervicalCheck arose from the way in which the disclosure to women happened, or rather, in the substantial majority of cases, did not happen. There was nothing in the briefing notes that would have indicated the major issues on non-disclosure that ensued or would reasonably have prompted any intervention on that issue from either the top of HSE or from the Department. The Scoping Inquiry notes that there were no subsequent briefing notes about the differences of opinion the majority of the colposcopists had with CervicalCheck on the issue of non-disclosure. Indeed, the final note, dated October 2016, which was passed to the Department, concludes with the reassuring sentence,

The communication with stakeholders and patients is being appropriately managed at this time.

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The full text of the notes sent to the Department and the emails and agendas with which they were associated, is in the public domain.¹⁹

On the basis of the information that has been available, the Scoping Inquiry believes that it would be unreasonable to expect senior management in the HSE and, even more so, Departmental officials, to have intervened on foot of the briefing notes. The subsequent problems were significantly associated with the failure to disclose, and it would have been difficult to predict this given the reassurance with which they were provided.

5.8 Recommendations

- 4) The Minister for Health should consider seriously the appointment of two patient advocates to the proposed new Board for the HSE.
- 5) A National Screening Committee should be constituted to advise the Department of Health and the Minister on all new proposals for screening and revisions to current programmes.²⁰
- 6) The NSS, whatever its location within the HSE, should be able to access senior levels of the organisation and be located close to strategically and logically linked services.
- 7) A far greater component of professional and public health expertise should be deployed across the screening services, not as external advisors but with significant roles within the screening programmes.
- 8) The implementation of new governance arrangements for the HSE should include a substantial revision to the organisational approach to risk management and its reporting.

¹⁹ This documentation is available at https://health.gov.ie/wp-content/uploads/2018/05/180515_CervicalCheck_Departmental-2016-Documents.pdf

²⁰ A draft specification for such a committee has been drafted by the Scoping Inquiry and is attached at Appendix 4.

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6 CervicalCheck – Laboratory Services

6.1 Introduction

The functioning of an effective cervical screening service depends on the availability of cytology laboratory facilities to test samples taken as part of the CervicalCheck process. Since the inception of the CervicalCheck programme, a number of laboratory companies have been engaged to undertake the testing of samples:

- Quest Diagnostics, Inc., of Trenton, New Jersey, USA;
- Laboratories owned by Sonic Healthcare, a global healthcare company whose headquarters are in Sydney, Australia, and which includes:
 - Clinical Pathology Laboratories (CPL) of Austin, Texas, USA;
 - MedLab Pathology Ltd (MLP) of Sandyford, Dublin, Ireland;
 - The Doctors Laboratory (TDL) of London, UK;
- Coombe Women & Infants University Hospital, Dublin.

(As reported in Section 6.8.4 below, the Scoping Inquiry identified a further five laboratories in the US which had been used by Sonic Healthcare as part of the CervicalCheck contract held by CPL between 2010 and 2013.)

6.2 Timeline for CervicalCheck Laboratory Services

The timeline showing each company's involvement in the CervicalCheck programme is presented below:

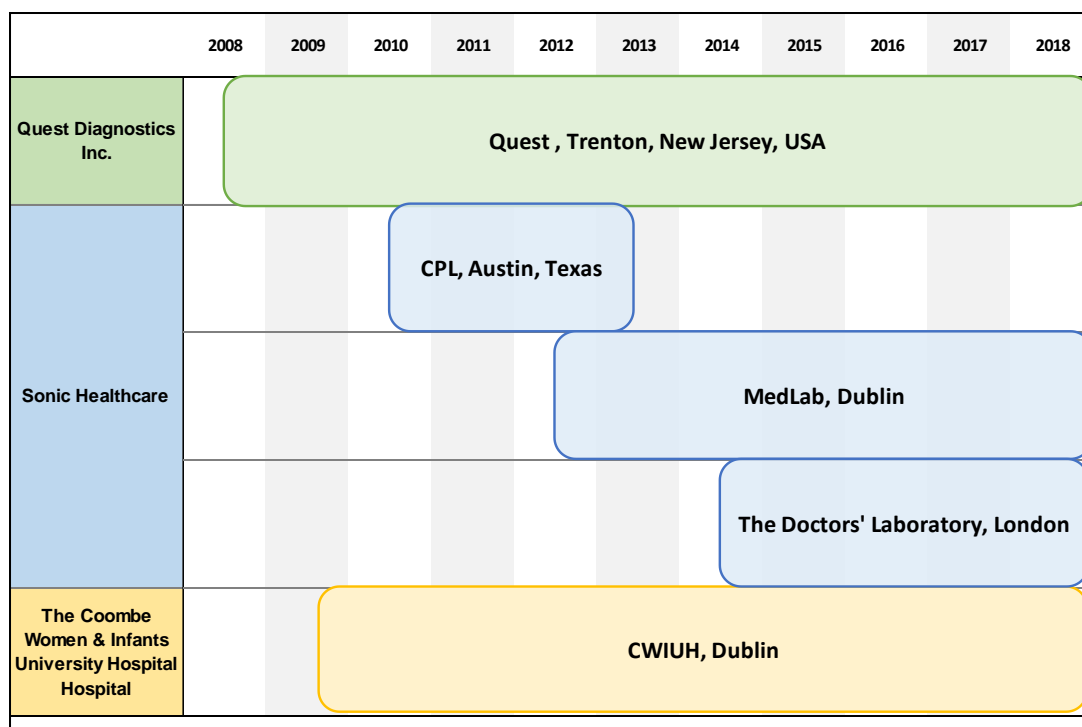


Figure 6.2-a: Timeline of Laboratory Service Provider Contracts with CervicalCheck

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6.3 CervicalCheck Testing Volumes

Over the lifetime of the CervicalCheck programme, the number of samples provided by women participating in the programme is **3,134,326**.

Notably, CervicalCheck has not been able to provide this number broken down in detail by laboratory for the entirety of the programme. The percentages are very approximately apportioned:

- Quest Diagnostics - 45%
- Sonic Healthcare - 45%
- Coombe Women & Infants University Hospital - 10%

The number of samples reported on by MLP and Quest Diagnostics are summarised below:

Year	MLP	Quest	Total (MLP + Quest)
2008		25,279	25,279
2009		156,243	156,243
2010		177,024	177,024
2011		169,942	169,942
2012	113,799	171,106	284,905
2013	173,163	188,044	361,207
2014	128,169	138,287	266,456
2015	126,262	133,876	260,138
2016	124,382	132,075	256,457
2017	131,753	132,630	264,383

6.4 CervicalCheck Laboratory Processes

Typically, the processes employed by the laboratories in CervicalCheck work involve a series of sequential steps. Boxes of samples are received and opened by the laboratories in a designated reception area, and various administrative tasks are undertaken, including accessioning (the formal receipt and logging of specimens for laboratory testing). A series of scientific processes then applies within the laboratory, and samples are screened and checked by cytotechnologists or medical scientists. Reports are prepared and slides are filed and stored within an archive.

For the US laboratories involved in CervicalCheck testing, US customs and transportation security procedures apply when the boxes of samples arrive in the US, and it will generally take no more than 24 or 48 hours for the samples to clear customs and security, but occasionally there are longer delays.

Although the specific processes employed in each laboratory differ slightly, the diagram overleaf shows the sequence of tasks involved at the MLP facility at

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Sandyford in Dublin, which is illustrative of the typical steps in the processing of cervical tests. Section 6.8 describes some of the specific processes employed at each of the laboratories which members of the Scoping Inquiry team visited during the course of this review.

1: Box Opening

- Date stamp test request form (TRF)
- Match form and vial using First name, Surname and DOB
- Check vial number against test request form
- Check vial for near expiry by checking date of collection
- Separate out queries/discrepancies
- Separate out Colposcopy samples requiring HPV testing / HPV only tests / Private samples
- Vials placed into labelled T5 trays and TRF's left with tray of vials to be accessioned

2: Accessioning

- TRF's given an episode barcode number in Prep Lab
- Samples booked into Laboratory Information Management System (LIMS) using episode number which generates accession barcode to label up vial and form
- Full check of form and vial done during this step
- Dr ID code, surname, first name initial, sample site, consent and if HPV test is required is entered into LIMS
- Queries separated out to go to Discrepancies Dept.
- Bloodstained samples (2+ out of 3 score) are separated out to be pre-treated before processing
- Samples placed on automated instruments to be processed

3: Processing

- Sample trays loaded into T5 instruments in Prep Lab
- Instrument batch reports are printed and reconciled with slides in alcohol baths
- Failed samples where instrument errors take place are placed on next tray to be re-processed
- Processed slides in alcohol baths loaded onto automated stainer/coverslipper
- Processed sample vials unloaded from T5's scanned into storage for 6 weeks

4: Data Entry

- Accessioned forms are taken to data entry area to be given full data entry into LIMS
- All hardcopy TRF's scanned into designated folder on the network for later retrieval
- Queries separated and sent to Discrepancies Dept.
- Previous history is merged with current sample if criteria are met
- Data entered forms are quality controlled by a second person
- Hardcopy TRF's stored for 6 weeks

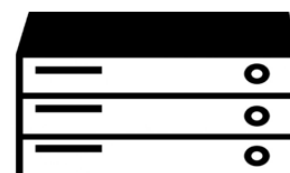
5: Staining, Coverslipping, Incubation and temporary storage of slides

- Slides stained & coverslipped using automated instruments in Prep Lab
- Racked slides are left in incubator overnight on low temp to facilitate the drying process
- Dried slides are placed in numeric order in temporary labelled slide drawer storage to be carried to Screening Room
- Slides are placed in designated shelving to await screening & reporting

6: Screening and Reporting

- Slides placed onto trays for transfer to microscope station to be primary screened
- Primary screened slides are resulted into LIMS once verified against scanned TRF
- Primary screened slides deemed negative / unsatisfactory are separated and quality controlled by rapid review
- Primary screened slides which require target rescreen are separated out into checker box
- Quality controlled slides are authorised in LIMS by rapid reviewer
- Target rescreens are given full manual rescreen by checkers
- Abnormal target rescreens are placed in pathologist box for authorisation
- Negative target rescreens are authorised by checker
- Abnormal cases are reported out by pathologists
- Daily paper copy reports printed and electronic reports generated for cases authorised
- MDT sessions held with colposcopy clinics

7: Slide Storage and Archiving



- Slides filed according to accession number in numeric order per year
- Slides stored for 10 years

Figure 6.4-a: Sequence of Tasks Involved at MLP (Sandyford, Dublin)

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6.5 Procurement History

Section 7 of this report sets out a detailed description of the procurement history, along with assessment and analysis of the procurement competitions run and contracts awarded by CervicalCheck.

6.6 Contracts

The historical and existing contracts are summarised in the table below.

Year	Quest Diagnostics	Sonic Healthcare (or subsidiaries)	Coombe Women & Infants Hospital
2008	Two-year Contract #1 (with two-year extension option)		
2009			Subcontract from Quest Diagnostics for the purposes of cytologist training in CWIUH
2010	Contract #1 extended	Two-year Contract #1 (with two-year extension option)	Memorandum of Understanding between the NSS and CWIUH for the provision of cytology services through cytologist training.
2012	Multi-vendor framework contract Two-year contract #2 (with optional two-year extension)	Multi-vendor framework contract New two-year contract #2 (with optional two-year extension)	
2014	Contract #2 extended	Contract #2 extended	
2016	Contract #2 extended (for the second time)	Contract #2 extended (for the second time)	
2017	Contract #2 extended (again) past its duration pending new competition in 2018	Contract #2 extended (again) past its duration pending new competition in 2018	

6.7 Service Providers

6.7.1 Overview

Members of the Scoping Inquiry team visited all of the laboratories contracted to provide cytology screening services to CervicalCheck during the course of the review. The following paragraphs provide a brief description of the laboratories in question, drawn from a combination of published material and information obtained during the Scoping Inquiry's engagement with the laboratories, and Section 6.8 describes and discuss the quality arrangements in place within each. Section 6.9

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presents an analysis of the laboratory services, following which a series of recommendations is presented in Section 6.12.

6.7.2 *Quest Diagnostics, Inc.*

Quest Diagnostics Incorporated, based in Secaucus, New Jersey, describes itself as ‘the world’s leading provider of diagnostic information services’. Quest Diagnostics was incorporated in Delaware in 1990; its predecessor companies date back to 1967.

Quest runs laboratories, patient service centres, offices and other facilities around the United States and in selected locations outside the US, including Puerto Rico, Mexico, India and Ireland.

Key features of the business include:²¹

- It employs around 20,000 phlebotomists, paramedics, nurses and other health and wellness professionals, mainly in the US;
- In 2017, Quest processed approximately 164 million test requisitions across its operating locations;
- Quest generated net revenues of \$7.7 billion in 2017.

With specific regard to CervicalCheck, Quest operates a facility near Dublin airport in which samples are received and accessioning takes place. These samples are then flown from Dublin to John F. Kennedy International Airport in New York, and – having cleared US customs and security – are transported by road to the Quest laboratory in Teterboro, New Jersey, where the screening is performed.

6.7.3 *Subsidiary Companies of Sonic Healthcare*

Sonic Healthcare describes itself as ‘a global healthcare company with a reputation for excellence in laboratory medicine/pathology, radiology/diagnostic imaging and primary care medical services’.

Headquartered in Sydney, Australia, there are companies operating in Australia, the US, Germany, Switzerland, the United Kingdom, Belgium, Ireland and New Zealand.

In discussions with members of the Scoping Inquiry team, senior representatives of companies within Sonic Healthcare referred to it as a ‘federated group’, with each firm having operational autonomy. The Sonic 2017 Annual Report states:

Sonic’s operations are structured as a ‘federation’, with individual subsidiaries or geographical divisions working in a synergistic network to achieve best practice outcomes in terms of service and business excellence. The structure reinforces the identity and management autonomy of each local operation. Each operation has its own CEO or

²¹

Source: Quest Diagnostics Inc. 2017 Annual Report on Form 10-K

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President and management team. When Sonic acquires businesses, they generally maintain their management autonomy, brand, and consequently their local 'flavour'.

The companies employ around 34,000 people, and in the full year ending 30th June 2018 it reported a statutory net profit of A\$476 million (equivalent to €300m), on revenues of A\$5.54 billion (€3.49bn).

Within the US, the laboratory businesses include a range of subsidiary companies which typically cover a specific territory or functional/scientific field. According to the website, there are 12 companies servicing the US, across multiple locations ²².

With specific regard to CervicalCheck, the companies which have been contracted to conduct testing of Irish samples are the following:

- Clinical Pathology Laboratories of Austin, Texas, USA;
- MedLab Pathology Ltd (MLP) of Sandyford, Dublin, Ireland;
- The Doctors Laboratory (TDL) of London, UK.

In 2016, TDL commenced what has been described as 'a progressive partnership' with Royal Free London NHS Foundation Trust (the Royal Free London) and University College London Hospitals NHS Foundation Trust (UCLH) to establish Health Services Laboratory (HSL). The new laboratory, which is jointly-owned by Sonic Healthcare and its NHS partners, has been established to provide medically-led diagnostics, innovation, value and long-term investment in healthcare, and serves a predominantly NHS client base.

6.7.4 Coombe Women & Infants University Hospital, Dublin

The Coombe Women & Infants University Hospital (CWIUH) is a voluntary sector hospital which has charitable status. It is a university teaching hospital affiliated with Trinity College Dublin.

The Hospital hosts the Cellular and Molecular Cytopathology Training School, which offers training to biomedical scientists, pathologists in training, and colposcopy staff. The training is focused on the current needs of CervicalCheck and also on changing needs in the future, with a particular emphasis on preparing a workforce for the introduction of molecular techniques into cervical screening.

In order to ensure that the expertise required for cytology training is maintained, CWIUH is working to a memorandum of understanding to deliver a minimum of 25,000 and a maximum of 35,000 cervical cytology reports annually to CervicalCheck.

²²

Source: <https://www.sonichealthcare.com/services/laboratory-medicine-pathology/usa/>

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The laboratory is also very research-focused with extensive grant funding for world leading research in the field of molecular pathology. There is an outstanding record of publication and postgraduate study.

The cervical cytology and HPV service is embedded within a department which also processes and reports histology specimens and there is a close clinical working relationship with colposcopy, which is also on site.

6.8 Quality

6.8.1 *How Laboratory Quality can be Assured*

Quality assurance of laboratories and indeed other parts of a cervical screening programme is a well-established process. Key aspects are:

- Detailed specification of the standards of service which are to be provided;
- These standards will include both process and outcome;
- The provider must be compared to standards for process and outcome;
- Methods of doing this include:
 - Self-declaration;
 - Analysis of outcomes by means of standardised data returns, and internal analysis of data for quality monitoring purposes;
 - Inspection via a visit to the premises and assessing performance by comparing to process and outcome standards (QA Visit);
 - Audit.
- Follow up of interventions taken as a result of any quality issues identified, and documentation of responses and progress towards resolution.

Analysis of screening performance through data is a key activity for a screening programme. It provides an evidential basis for the quality assurance of the programme. In cervical screening, the key indicators informed by data are:

- Capacity: Which indicates simply the volume of samples processed and the turnaround times for processing.
- Specificity: Specificity is linked to the validity of a laboratory's screening results. It is indicated by comparison between the cytology outcome and subsequent clinical biopsy and proven disease. (In simple terms: if a positive screening result is confirmed by a diagnosis.) This is important to avoid overtreatment, but can be complicated by variations in histology and colposcopy practice.
- Sensitivity: Sensitivity is **the key metric**, as it determines how likely screening is to detect abnormalities. It can be measured in a number of ways:
 - Individual screener sensitivity – comparing the initial screen result with a second screen within the laboratory.

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- Measurement of the detection rate for abnormalities (especially high grade abnormalities) by a member of staff and by the laboratory as a whole.

Sensitivity metrics are finely contextualised, as the true rate of abnormalities in a screened population will vary according to a range of factors including age, socioeconomic status, smoking status, ethnicity, how well-screened the population is, and use of HPV testing or vaccination. Women already known to have an abnormality have a much greater likelihood of having an abnormal result.

Robust procedures and agreements are required to be in place and must be in line with international effective practice norms.

Quality assurance mechanisms are not designed to ensure a particular cancer detection rate, but they are concerned with the quality of the laboratory processes. Reliability and validity underpinned by sound processes and evidenced by data is the cornerstone of a modern standardised and predictable process.

The material presented in the following paragraphs sets out the observations and assessment of the Scoping Inquiry, following site visits to each of the laboratories engaged by CervicalCheck and analysis of documentation made available to the Scoping Inquiry.

6.8.2 *Quest Diagnostics, Inc.*

Liquid-Based Cytology (LBC) vials are collected from the sample taker and transported to a Quest-owned facility located near Dublin Airport. Samples are accessioned on the Quest laboratory information system (LIS). The request form is sent with the vial and scanned and stored.

The workload has typically averaged about 500 samples per day, but this has been very variable.

In recent weeks, the volume of samples coming to Quest has seen marked increases, and on the day before the Scoping Inquiry's visit (in late July 2018) Quest had received 1,400 cases. The indication from Quest was that they would be unable to cope with this workload for a sustained period, and were hoping that it reduces as anticipated in the summer.

Sometimes, there can be delays when samples get delayed at US customs or security. It is Quest's aspiration to report all samples within 48 hours, but this is currently not possible.

The entire pathway is delivered at the Quest facility at Teterboro NJ. For approximately two years from the start of the contract in 2008, a Quest laboratory in Wood Dale, Illinois, was used. The Scoping Inquiry is satisfied that there is no current outsourcing of any Irish work, including back-office functions, administration, finance,

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or other functions. All staff employed by Quest at the Teterboro laboratory, both pathologists and cytotechnologists, hold substantive positions within the company.

Quest's Teterboro laboratory is a large cytology provider and the CervicalCheck work represents a minority of the samples reported at that location. Workflows are well separated between CervicalCheck work and that for other clients.

Individual slides are prepared for each vial received by etching the number onto glass. It is reported that occasionally this stage picks up labelling issues: this is a double check for matching already done in Ireland and at specimen reception.



LBC preparation (ThinPrep) is undertaken with banks of T2000s (*illustrated left*: an automated slide preparation system, for use with the ThinPrep pap test). Each operator runs three platforms. Strict rules have been put in place to ensure an intact chain of custody. Quest stated that they had not had a custody error / mismatch 'for years'.

All samples are prepared in accordance with the ThinPrep Imaging System (TIS) which requires specified slides and staining protocols. The TIS automatically scans every cell and cell cluster, highlighting areas of interest for human analysis. The system marks the 22 fields of view (FOV) most likely to be abnormal (referred to as '22FOV') for manual interpretation. (The Hologic ThinPrep Imaging System is shown on the right as an illustration of the type of equipment used by Quest.)



HPV testing, when required, is performed using the Hologic Aptima system – this is the only stage where workstreams are done together, but separate numbering ensures no confusion. The Tigris (a large automated HPV testing platform) is networked into the LIS, with direct upload of HPV results.

Irish slides are only HPV-tested according to protocol, which is currently triage of ASCUS and LSIL samples, and for test of cure.

Screeners work in a comfortable office in personal cubicles. Many are decorated with certificates and awards, personal photos, etc. Each has a microscope and computer with access to multiple databases to check history for Irish slides.

A full manual screen is undertaken as the first screen. Results are entered by the cytotechnologist.

The second screen is image assisted, using the TIS. If this is negative, no second manual screen is undertaken. If the 22FOV gives cause for concern, a full manual screen is undertaken.

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Some high-risk samples are taken out for full rescreen, regardless of 22FOV – these are defined from the screening history – i.e. symptomatic, abnormal cervix, or a previous abnormal finding.

The referral rate to a pathologist for further review was stated by Quest to be in the region of 15%.

Quest believes that about 50% of ASCUS²³ findings are HPV+ but this is not a monitored data item for the Irish work – the figure is based on their whole workload, which includes a significant amount of co-testing.

Most of the Quest staff are trained for working on the CervicalCheck contract to Irish specifications, but only do either Irish or non-Irish work each day. CervicalCheck work represents about 20% of the total workload of the Quest laboratory in Teterboro. Different rules apply for specimens from New York and other states, and for Ireland, in terms of maximum number of cases to be handled per day by each screener. Careful record keeping of the workload is maintained to ensure compliance.

Many of the staff at the Quest laboratory in Teterboro have been employed there for a long time. During the site visit, introductions were made to a large number of staff with more than 25 years' experience, including one individual with over 40 years' service (in specimen reception). Many staff indicated that Quest was a good place to work. There was evidence of good engagement between management and staff, good internal communications, and support for training and staff development. The Scoping Inquiry was advised that there were some vacant cytotechnologist posts.

Quest undergoes CAP (College of American Pathologists) accreditation every two years, and the Teterboro laboratory usually passes with very few non-conformities. However, CAP accreditation achieved by Quest (and by CPL) is not the same as the ISO standard required under the CervicalCheck contract: this is a matter which is assessed in more detail in Section 6.8.5 below.

Quest Diagnostics' approach to data collection and analysis appears very thorough. Staff were able to share and discuss standardised data used in their US practice and their mandatory quarterly returns to Ireland. Annual data on reporting rates are collated by the laboratory itself as CervicalCheck does not share or provide data on this. Benchmarking is therefore a significant challenge as Quest does not have an expected abnormality rate for the Irish population; so it is required to benchmark itself against its own historical data and results for other workstreams (despite knowing that the actual rates are likely to be different).

²³

ASCUS is defined as 'A finding of abnormal cells in the tissue that lines the outer part of the cervix. ASCUS is the most common abnormal finding in a Pap test. It may be a sign of infection with certain types of human papillomavirus (HPV). It may also be a sign of a benign (not cancer) growth, such as a cyst or polyp or, in menopausal women, of low hormone levels. More testing, such as an HPV test, may be needed. Also called ASC-US and atypical squamous cells of undetermined significance.' (Source: US National Cancer Institute. www.cancer.gov)

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In the most recent return (Q2 2018) there are some points of interest to support this.

- Screener sensitivities are mostly low to mid 90s across all results. On high-grade abnormalities, no screener in Quest on this return scored less than 95%, but there are relatively few 100% scores. This is as expected for a good laboratory and shows that the second screen is working well as a quality monitoring tool.
- Quest has demonstrated a supportive approach to screeners who miss targets and a robust policy for management is in place.

6.8.3 *Clinical Pathology Laboratories (CPL), Austin TX*

The CPL laboratory in Austin, Texas, received cervical cytology samples from Ireland for a period from 2010 to 2013. This was part of an agreement between the CervicalCheck programme, MLP, and CPL to deliver the service from Austin, while capacity was being developed and accreditation was being gained in MLP in Dublin. Around 300,000 samples in total were reported by CPL during this period.

The laboratory in Austin is a large facility, and during the site visit made by members of the Scoping Inquiry team there was much evidence of major investment in equipment and technology within the laboratory. It currently employs around 35 cytotechnologists and 10 pathologists in-house to support cervical cytology.

The laboratory is accredited by the College of American Pathologists (CAP) which administers a certification program that meets or exceeds the standards specified in the Clinical Laboratory Improvement Amendments (CLIA)²⁴. CAP accreditation is biannual with mandatory self-inspection in intervening years. CLIA inspectors may inspect the laboratory at any time to verify accreditation or respond to concerns. CPL was inspected and accredited by CAP in May 2018. The laboratory requested a reinspection in the light of adverse CervicalCheck press reports; this inspection was conducted in June 2018, which resulted in no deficiencies and reaffirmed certification. In addition, inspectors from US Centers for Medicare and Medicaid Services (CMS), acting under CLIA authority, inspected the laboratory in May 2018 with 5 cytotechnologists and 1 cytopathologist. They identified 99.5% diagnostic accuracy in 1,387 cases selected for random and focused review.

The Scoping Inquiry team was shown around this modern laboratory, fully equipped for HPV testing and using the TIS imager, but it is important to note that a significant proportion of the Irish work was not undertaken in Austin. CPL has confirmed that with regard to its CervicalCheck work, 'two-thirds of the screeners worked out of the

²⁴

Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. Three federal agencies are responsible for CLIA: The Food and Drug Administration (FDA), Center for Medicaid Services (CMS) and the Center for Disease Control (CDC). Each agency has a unique role in assuring quality laboratory testing. See: <https://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm>

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CPL Austin laboratory'.²⁵ However, this was not communicated to the Scoping Inquiry during this visit and it is notable that no data to quantify the amount of work undertaken elsewhere has been submitted.

In order to increase capacity sufficiently to undertake the Irish workload, CPL recruited staff to its pre-existing histology and cytopathology laboratory in San Antonio, Texas as well as to its main laboratory in Austin. (San Antonio is around 80 miles distant from Austin, and around two hours away by road.) The San Antonio site was staffed with a full-time supervisor and employed cytotechnologists who qualified as CLIA supervisors. Cases that met criteria for pathologist review were evaluated by San Antonio-based members of the pathology practice. All quality and productivity metrics were aggregated and managed through the CPL Austin laboratory site.

Sonic has advised the Scoping Inquiry²⁶ that the staff additions at the San Antonio laboratory were 'to access the large medical and military community there', although it was on a very much smaller scale than the main laboratory in Austin. In that context, the Scoping Inquiry understands that San Antonio is a national centre for cytology within the US military – the Scoping Inquiry understands this to be Brooke Army Medical Center, which is 'the largest and most robust military healthcare organization within the Department of Defense', employing over 8,500 personnel.²⁷ The University of Texas Health Science Center at San Antonio is also a major training location for cytologists.

The San Antonio site continued in operation until 2012 when the facility was incorporated into the hospital system for which the laboratory was originally established. All staff members were offered transfer, and the supervisor and four cytotechnologists were absorbed into the CPL Austin Main laboratory. The San Antonio facility was certified by CLIA.

It would appear, therefore, that a significant part of the Irish CervicalCheck work was undertaken by laboratory staff whose main employment was elsewhere in a training role, or in another role with little screening workload. This enabled them to undertake part time screening without breaching the CervicalCheck limit of six hours screening per day, or the CLIA limit of 100 slides per day.

The lead pathologist for the service is still in post within CPL, and has contributed recently to the audit of cervical cancer cases, but did not do so at the time. He was mainly responsible for the Multi-Disciplinary Team meetings, which he felt worked very well.

The CPL staff met during the site visit feel strongly that the service provided is of a very high quality and that it is a strength of their organisation; they are proud of it and

²⁵ Source: email from Sonic Healthcare to the Scoping Inquiry dated 3rd September 2018

²⁶ Source: email from Sonic Healthcare to the Scoping Inquiry dated 3rd September 2018

²⁷ Source: <https://www.bamc.amedd.army.mil/bamc-facts.asp>

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distressed by the adverse publicity. They did express the view that communication with the CervicalCheck programme in both directions could have been better.

6.8.4 *Involvement of Other Sonic Healthcare Subsidiary Laboratories*

Given that the CervicalCheck contract awarded to Sonic in 2010 only stipulated Austin as the cytology testing location, the Scoping Inquiry was surprised to learn in response to questions during the site visit that a significant proportion of tests within the CervicalCheck programme had in fact been undertaken in a much smaller facility in San Antonio, Texas. The Scoping Inquiry's understanding was that Schedule 13 of the contract did allow workload to be transferred to other Sonic sites, under the heading 'Storage and Disaster Recovery Plan'.

Schedule 13 of the contract states the following:

SCHEDULE 13

Storage and Disaster Recovery Plan

Sonic Healthcare Ireland Ltd is committed to developing a laboratory in Ireland that will have increasing capacity to undertake the cytology tests, although initially all the tests will be undertaken in Austin, Texas. In the event that CPL in Austin unexpectedly is unable to provide cytology services, workload can reliably be handled at other Sonic Group laboratories in the United States.

It is anticipated that personnel from CPL could be transferred temporarily to these Sonic Group laboratory to provide the labour needed for the shifted workload. All Sonic Group laboratories in the US have compatible policies, procedures and IT systems with CPL. The necessary communication links are also already in place to facilitate the almost instant transfer of the tests.

Further should there be any communication or transport disruption to the United States then TDL in London has the capacity, at least in the short term, to undertake all the tests required in Ireland or if necessary the test could readily be accommodated in Sonic's Australian laboratories.

The precise meaning of Schedule 13 is somewhat unclear, as are the circumstances associated with a laboratory being 'unexpectedly... unable to provide cytology services'; these matters require further consideration.

Against that backdrop, at the conclusion of the Austin site visit a follow-up question was posed to CPL, asking the company to confirm whether, other than Austin and San Antonio, any other CPL / Sonic facilities were involved in performing work for CervicalCheck. The response received stated the following:

CPL Main in Austin, TX performed the majority of CervicalCheck primary and secondary screenings with CPL auxiliary sites in San Antonio, Texas, Victoria, Texas and Las Vegas, Nevada acting as primary screening sites. With a small surge at program establishment in 2010, a limited number of accessions were distributed in accordance with Schedule 13 of the initial CervicalCheck contract to two Sonic Healthcare USA (SHUSA) affiliated

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laboratories, Honolulu, Hawaii and Orlando, Florida for primary screening with secondary review and authorization at CPL Main.²⁸

Both HSE senior management and CervicalCheck staff and managers were asked whether they had been aware of work being undertaken for the CervicalCheck programme at Sonic laboratories in Victoria TX, Las Vegas NV, Honolulu HI, or Orlando FL, and the Scoping Inquiry was advised that there was no such awareness within CervicalCheck, NSS, or the wider HSE.

Sonic Healthcare was asked for comment on the invocation of the Schedule 13 provisions. Sonic replied:

We would like to highlight that there was no breach of the contract within the USA on the use of two Sonic Healthcare Laboratories within the contracted period of 2010. It is clearly stated within schedule 13 of the 2010 contract that

“In the event that CPL in Austin unexpectedly is unable to provide cytology services, workload can reliably be handled at other Sonic Group laboratories in the United States.”

... there was a large volume of patient samples received at the end of 2010. ... CPL required support to screen these samples and utilised two Sonic Healthcare facilities for a short period of time (3 weeks).

This specifically refers to the Honolulu and Orlando laboratories, but makes no reference to the use of the laboratories in Victoria and Las Vegas.

There is no record available to the Scoping Inquiry that would suggest that CPL advised CervicalCheck of either the use of these laboratory facilities or any conditions that might be judged under Schedule 13 to require the use of these facilities. This matter will be the subject of further investigations by the Scoping Inquiry and covered in a supplementary report.

To further examine this matter, the Scoping Inquiry also searched all 12,800 documents provided by the HSE, Department of Health, and other entities, for any references to the laboratories in San Antonio, Victoria, Las Vegas, Orlando, and Honolulu. There were no references found in any document to the laboratory in Orlando. In regards to the Honolulu laboratory, the only reference was an indirect one to the Sonic Hawaii companies, found within the Sonic Healthcare Group structure chart dated 2009 (supplied as part of a procurement process). The two Texas laboratories and the Las Vegas laboratory are mentioned in the MLP tender submission in 2012, which listed the laboratories alongside the Austin, TX laboratory in the ‘Staff Resources’ section of the submission. The tender evaluation report notes

²⁸

Source: document supplied by CPL on 10th August 2018 to the Scoping Inquiry

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that: 'The organisational chart provided is linked to teams from Las Vegas and does not refer to front line staff that will look after this contract.'

This confirms the conclusion of the Scoping Inquiry that CervicalCheck, the HSE, and the Department of Health were not advised by Sonic of the involvement of any of these laboratories, other than Austin, in the servicing of the contract.

A number of questions arise from CPL's disclosure of the other four laboratories:

- What is/was the nature of the two additional 'CPL auxiliary sites' in Victoria, Texas and Las Vegas, Nevada? Do they still exist or, like the site in San Antonio, Texas, have they been discontinued? What other work goes on there? What is their scale and size? [Preliminary research would suggest that CPL currently operates multiple sites in both Victoria and Las Vegas.]
- What is/was the nature of the 'two Sonic Healthcare USA (SHUSA) affiliated laboratories' in Honolulu, Hawaii and Orlando, Florida? What does 'affiliated' mean? Are these laboratories part of Sonic or are they independently owned?
- What was the volume of CervicalCheck tests performed in each of these four laboratories?
- What was their compliance with quality and regulatory standards?
- What were the reporting and governance arrangements in place for each of these four laboratories?
- What were the circumstances which led to work being transferred from Austin to other sites?
- Did CPL inform CervicalCheck of workload being transferred to other sites? Were such transfers approved?

Subsequent to the disclosure by CPL of the involvement of the additional laboratories, further correspondence was received by the Scoping Inquiry from the CEO of Sonic Healthcare, stating the following:

CPL participated in the CervicalCheck program from 2010-2013 during which, a total of 326,260 CervicalCheck cases were reported. Within this same period, CPL reported more than 2.5 million cases unrelated to CervicalCheck. The breakdown by year of service for the Irish cases is indicated below.

	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
<i>Irish Case Volume:</i>	61,866	163,530	95,233	5,631

These cases were reported within the CPL network of CLIA and CAP accredited cytology laboratories including CPL Austin, CPL San Antonio, CPL Victoria and CPL Las Vegas. All these laboratories are an integral part of CPL and are operated under a single medical, operational and quality management structure and all contributed to the overall screening capacity

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that CPL was required to maintain under the terms of the CervicalCheck program. As these laboratories are all part of CPL's integrated regional laboratory network, we believe that the utilization of all of these cytology screening sites was appropriate under the contract. While these are geographically separate facilities, they are all part of the networked CPL laboratory group.

During the first year of service, when CervicalCheck workload was progressively being transferred to CPL, fluctuations in slide volumes arriving in the laboratory occurred. Due to logistical issues relating the transportation of slides from Ireland to the US and processing by US Customs short term critical capacity pressures occurred. To meet contractual obligations relating to turn around time, CPL needed to urgently and temporarily increase screening capacity. This was achieved by utilizing excess capacity in two other US-based Sonic Healthcare laboratories – CPLSE in Orlando, Florida and Clinical Laboratories of Hawaii (CLH) in Honolulu. In total, 300 cases were screened at CPLSE and 250 at CLH in 2010. Together, these cases represented less than 1% of the total 61,866 CervicalCheck cases screened by CPL in 2010. Please note that only the initial primary screen was performed at these laboratories while secondary screening and pathologist review continued to be performed at CPL Austin and CPL San Antonio.

It is important to emphasize that all CPL and Sonic Healthcare US laboratories that performed screening services were fully accredited and of the highest quality, and all screening services were performed in accordance with the HSS quality criteria. The temporary use of non-CPL laboratories was an action that was taken as an exigency measure to maintain turn-around times required for optimal patient care.

In our assessment of the CervicalCheck contract, rebalancing workload to other non-CPL Sonic Healthcare laboratories within the US was contemplated by the contract as a necessity to meet service needs and our ethical obligation to provide screening as timely as possible. We acknowledge that we should have notified the CervicalCheck program of the screening at other SHUSA laboratories. If we did in fact fail to make this notification we apologize however, 8 years after the fact and as a result of the subsequent departure of key personnel, we are unable to identify documents to confirm whether or not this notification occurred.

In summary, an insignificant number CervicalCheck cases were reviewed in non-CPL laboratories during 2010 in order to address an acute capacity deficit related to surges in workload arriving in the laboratory due to logistical issues. All screening was performed to the highest quality standards by highly qualified and experienced cytologists working in fully accredited, Sonic owned laboratories and under the supervision of key CPL medical and scientific personnel. We believe that the use of non-CPL

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*laboratories was contemplated under the terms of the contract in acute circumstances in order to meet contractual obligations and duty of care.*²⁹

This additional information from Sonic Healthcare raises a number of questions which, at the time of writing, have yet to be explored in detail.

The Inquiry acknowledges that all affected parties were given a short time-frame within which to reply to requests from the Scoping Inquiry, dictated by the urgency of the issues involved and the necessity to submit the report to Minister as quickly as possible. Further evidence will be investigated and covered in a supplementary report. The Inquiry is grateful to Sonic Healthcare for its prompt and considered engagement with its team in relation to the issues which have arisen as set out above.

6.8.5 Accreditation of US Laboratories

Under the 2010 contract for provision of cytology services to CervicalCheck, the following accreditation standard was stated to apply:

4. Obligations of the Contractor

- 4.1 The Contractor shall ensure that each Laboratory shall hold and maintain for the duration of the Term third party accreditation from a recognised accreditation body (the "Accreditation Body") to a minimum of International Standard ISO 15189 (Gynaecological Cytopathology Medical Laboratories – Particular Requirements for Quality and Competence for Screening Liquid Based Cytology (LBC) Cervical Slides) or to such other standards as the Board at its sole discretion considers are not less than equivalent thereto ("the Accreditation Standards").
- 4.2 Prior to the execution of this Contract and at any time thereafter at the Board's request the Contractor shall provide the Board with such evidence as the Board shall require to verify that each Laboratory satisfies the Accreditation Standards. If during the Term, any Laboratory ceases to satisfy the Accreditation Standards or the Contractor reasonably believes that any Laboratory may cease to satisfy the Accreditation Standards, it shall notify the Board immediately and the provisions of Clause 18 shall apply.

This suggests that the core requirement was for ISO 15189 accreditation³⁰ or another standard which is 'not less than equivalent to' ISO 15189.

This requirement is further supported by a quality assurance document from the National Cancer Screening Service, as shown below (highlighting is from the original NCSS document, supplied to the Scoping Inquiry as a scanned hard copy):³¹

²⁹ Letter dated 24th August 2018 from Dr Colin Goldschmidt, CEO, Sonic Healthcare, to Dr Gabriel Scally

³⁰ This standard from the International Organization for Standardization specifies requirements for quality and competence in medical laboratories. See <https://www.iso.org/standard/56115.html>

³¹ Source: NCSS document *Quality Assurance in Cytopathology*.

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5.2.4.3.3 Accreditation

The laboratory must be **ISO 15189** compliant

Evidence of compliance with **ISO 15189** from the relevant competent accrediting authority must be provided to the NCSS

Any change in accreditation status must be immediately notified to the NCSS

From analysis of the material provided by the US laboratories, neither Quest or CPL has ISO 15189 accreditation – this was disclosed to members of the Scoping Inquiry team during the site visits in July 2018. Both laboratories do have CAP (College of American Pathologists) accreditation which they view as being equivalent. Quest Diagnostics publishes the current CAP accreditation certificate for each of its US laboratories on its website; the Teterboro certificate, as shown below, confirms that it is accredited under the CAP Laboratory Accreditation Programme.



The College of American Pathologists certifies that the laboratory named below

**Quest Diagnostics Inc
Clinical Laboratory
Teterboro, New Jersey
Lawrence Tsao, MD**

CAP Number: 1204101
AU-ID: 1177382
CLIA Number: 31D0696246

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to January 14, 2020 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Accreditation Committee

President, College of American Pathologists

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The CAP operates two accreditation programmes, which may be summarised as follows:

Accreditation programme	ISO 15189 compliance	CAP Definition	Personnel
CAP 15189	Provides ISO 15189 accreditation	<p>‘Voluntary in U.S.</p> <p>Developed through international expert consensus on medical laboratory best practices.</p> <p>Focus is on process—the overarching QMS, and the organization’s ability to sustain an integrated QMS approach across all parts of an organization with which the laboratory interacts’</p>	‘Full time ISO 15189 assessors, with backgrounds in quality management and medical laboratory work’
CAP LAP - Laboratory Accreditation Programme	Does not provide ISO 15189 accreditation	<p>‘Based on CLIA (required in US).</p> <p>Exceeds U.S. federal regulatory requirements</p> <p>Focus is on procedures—by integrating more stringent general and discipline specific requirements developed by our member experts with an emphasis on technical and procedural aspects in the laboratory’</p>	‘Volunteer peer assessors who currently work in medical laboratories’

CAP states that ‘CAP15189 and LAP are uniquely positioned to complement one another. This balance leverages the assurance of accurate patient diagnosis achieved through technical requirements of LAP with the CAP15189’s rigorous focus on sustainable quality management processes for all areas of an organization for which the laboratory interacts.’³²

The assessment of the Scoping Inquiry is that the CAP Laboratory Accreditation Programme and ISO/CAP 15189 are not the same. While both are recognised accreditation standards, the CAP LAP is designed to meet specific US regulatory requirements, whereas ISO 15189 reflects international best practice. The fact that ISO 15189 accreditation is administered by dedicated, full-time ISO assessors would suggest that it may be at a higher standard than the CAP Laboratory Accreditation Programme, which depends upon peer review.

CPL were asked to confirm whether their accreditation at the time of the contract (2010-13) was to ISO/CAP 15189 standard. CPL replied that ‘as CervicalCheck was

³²

Source: College of American Pathologists website http://www.cap.org/web/oracle/webcenter/portalapp/page_hierarchycap15189_accreditation_program.jsp?_afLoop=168252870422202#!%40%40%3F_afLoop%3D168252870422202%26_adf.ctrl-state%3D1a7vncuuoo_4

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aware and accepted at the time, the CPL laboratories were not accredited to ISO15189, but rather to CAP-LAP and CLIA standards'.³³

For the US laboratories, compliance with CAP requirements is primary, and the CAP indicates that its Laboratory Accreditation Program takes precedence and that accreditation to ISO 15189 is optional. The CAP states:

*The programs are distinctly separate but complementary; ISO 15189 does not fulfill US federal regulatory requirements. A laboratory that chooses to become accredited to ISO will experience a separate Laboratory Accreditation Program inspection from the ISO assessment.*³⁴

(The other laboratories involved in providing services to CervicalCheck, MLP in Dublin, TDL in London, and CWIUH in Dublin, are all accredited to ISO 15189.)

While it is certainly the case that both the Quest and CPL laboratories are compliant with US regulatory requirements, and that neither has had any significant issues with compliance in recent years, the fact is that neither is (or was) compliant with the apparent contractual requirement for ISO15189 accreditation

The Scoping Inquiry will investigate accreditation requirements and considerations further and undertake a comparative analysis of their application in the extended number of laboratories of which the Scoping Inquiry is now aware. These issues will be dealt with in the supplementary report.

6.8.6 Baylor College of Medicine – Use of CPL Austin Laboratories

In May 2018, it was reported in the US and Irish media that Baylor College of Medicine had 'launched a full review into the diagnostic accuracy of pap smears it sends to an Austin pathology laboratory that missed signs of malignancies in more than 200 Irish women later found to have cervical cancer'.³⁵

The Scoping Inquiry engaged with both CPL and Baylor College of Medicine in order to understand whether their review might have any relationship with, or implications for, the Scoping Inquiry. An audit conducted by CPL at Baylor's request showed a low diagnostic error rate, and as a consequence Baylor decided not to change its screening laboratory providers. (Official statements released by Baylor at the time are included in Appendix 2.)

³³ Email dated 28th August 2018 from CPL to the Scoping Inquiry.

³⁴ College of American Pathologists: *Frequently Asked Questions – ISO 15189 Accreditation Program*. See: <http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/15189-faqs.pdf>

³⁵ Including the Houston Chronicle <https://www.houstonchronicle.com/news/houston-texas/houston/article/Baylor-launches-review-of-company-s-cervical-12879896.php>

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6.8.7 *MedLab Pathology Ltd, Dublin*

MedLab Pathology Ltd (MLP), a wholly-owned subsidiary of Sonic Healthcare, was established in Dublin with the express purpose of repatriating the Irish screening workload from the US. It is accredited under ISO 15189:2012 which is an international standard for Medical Laboratories-Requirement for Quality and Competence. The last accreditation visit was in May 2018 and reported one minor noncompliance, which was easily rectified. This is an impressive result.

The Irish cytology screening workload began to be transferred from CPL to MLP in 2012 and the process was completed in 2013.

From the site visit, this appears to be a laboratory with robust processes. Full policy documents for key quality process steps were shared, and were clearly being well managed. Staff who met with the Scoping Inquiry team were engaged and open.

The laboratory normally processes between 130,000 and 175,000 samples per year. Since 2015, some of them have been sent to a further Sonic company in London, TDL (discussed in Section 6.8.8 below).

MLP has undertaken initial training of cytotechnologists to the level of accreditation as cervical cytology screeners in Ireland.

The MLP laboratory is currently experiencing a very substantial increase in workload and at the time of the Scoping Inquiry visit in late July 2018 was experiencing a backlog in cervical smear testing, with a turnaround time of eight weeks following the open invitation to cervical screening announced by the Minister for Health.

During this visit, the Scoping Inquiry was able to observe processes for specimen receipt, accessioning, processing and reporting, and report generation, all of which seemed robust.

MLP demonstrated an extremely thorough approach to data collection and management of quality. Routine data returns to CervicalCheck were produced and discussed. MLP used sophisticated data analytics software and had a dedicated technical resource for supporting this work.

MLP reported frustration with the apparent inability to gather up-to-date histology data from CervicalCheck, which affects its ability to assess its screen specificity. MLP demonstrated an exemplary understanding of the use of data to monitor the quality of screening.

Given the significant increase in CervicalCheck volumes experienced by MLP in recent months, Sonic were considering the option of sending screening to another Sonic facility in Sydney, Australia, and were in discussions with the HSE on this matter.

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6.8.8 *The Doctors' Laboratory, London*

The Doctors' Laboratory (TDL) is based in central London, is a subsidiary company of Sonic Healthcare and undertakes a significant amount of work for independent sector clients across the UK. TDL also provides contracted contingency (i.e. it can take on additional workload for other laboratories when they experience demand spikes). The work currently being undertaken for CervicalCheck is in this category. At the time of the Scoping Inquiry visit in July 2018, around 500 samples per week were being processed for the Irish CervicalCheck programme.

This laboratory is operating as a satellite of MLP for this work. It receives prepared slides already logged into the MLP LIS, to which it has full access. Slides are screened by qualified cytoscreeners and biomedical scientists. Abnormal cases are reported by a consultant pathologist, who acts as the lead for this service

TDL staff were aware of the Irish classification (P classification) for cervical cytology. Despite the P3b (ASC-H) category or equivalent not being used in the UK, the reporting pathologists' awareness and understanding of the Irish classification system is reflected in the reporting of a number of cases using P3b (ASC-H).

TDL's relationship with MLP is covered in a service level agreement. Staff explained that the medico-legal responsibility for any missed abnormalities rests with TDL, which along with MLP forms part of the Sonic Group.

The laboratory also carries out work on behalf of the NHS cervical screening programmes, where it operates under a tightly controlled Quality Assurance process.

To date only one sample has been reviewed as part of the audit. The TDL laboratory is not seen as a separate entity for statistical returns, which are all incorporated into the MLP return.

No HPV testing is carried out at TDL.

All processes in this laboratory appear to be well documented and robust, with a strong commitment to quality management evident amongst the staff with whom the Scoping Inquiry team engaged during the site visit. TDL functions as an integral part of MLP in regard to data collection and analysis (as mentioned previously). TDL staff, however, remain identifiable within the MLP returns to CervicalCheck. The majority of TDL's work is for the NHS in England, and it appears that they have a robust approach to data collection and management.

6.8.9 *Coombe Women & Infants University Hospital, Dublin*

This unit receives samples from multiple colposcopy clinics, including at the Coombe Women & Infants University Hospital (CWIUH), and five primary healthcare settings. The usual annual workload is around 25,000 samples; of these 25-30% are said to

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be sourced from colposcopy. There is also an additional small private cervical screening workload (around 5% of total laboratory throughput).

CWIUH bid for the initial contract award in 2008 as part of a consortium with two other hospitals, one of which was in Northern Ireland. However, the bid was unsuccessful. Staff understood that the reason was that only one of the three centres was accredited at the time (by CPA UK). CWIUH was well advanced in the process of achieving ISO 15189 accreditation: this was awarded in February 2009, and has been in place since this time.

Vials to be screened are accessioned onto the laboratory information system (LIS). Processes for checking patient identity are robust. Screening histories are automatically imported into the LIS following an exchange of information with CervicalCheck.

Workflow follows a similar pathway to that described elsewhere. The laboratory uses a T5000 automated processor to produce ThinPrep slides. These are then stained with the imager specific stain and analysed using the ThinPrep Imaging System (TIS). To this stage the process is completed within 48 hours of receipt.

Slides are then placed into a queue for manual screening, for which there is currently a backlog amounting to some 5,000 slides. At the time of this visit, samples being screened were taken in late June (approximately 9-10 weeks' delay).

There are 8.5 cytotechnologists who are all graduates, accredited for screening by the relevant bodies. There is a checker role and there are two consultant cytopathologists. All substantive posts are currently filled.

The pathway is that the TIS identifies 22 fields of view which are then reviewed in what is perceived to be a 'Rapid Pre-screen'. This results in a classification of either negative or abnormal on the LIS. All samples then undergo a full manual screen, and the results of the pre-screen are available to the member of staff undertaking this. Samples which are negative with both approaches are then authorised directly on the LIS, generating a report. Samples where either screen is abnormal are seen by a checker and, following a consensus process between cytotechnologists, all slides thought to be abnormal are sent for pathologist reporting. Pathologists would also review cases where either screen had been reported as High Grade.

This is clearly a well-thought-out system and reflects the extremely good staff communications within the laboratory, but it does not allow independent assessment of the two screens for screener performance monitoring, and this is reflected in very high levels of sensitivity recorded in individual performance monitoring. Most staff have 100% high grade sensitivity and no member of staff had an all-grade sensitivity of less than 96% in the last two years.

The CWIUH laboratory participates in the PHE slide exchange EQA (External Quality Assurance) system, although their results are not included in the analysis. No

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screener has been identified as a poor performer. They are also undertaking laboratory technical EQA.

Samples requiring HPV testing are in two categories:

- Community samples will be submitted to HPV triage in the presence of ASCUS or LSIL
- Samples from colposcopy comprise those requiring test of cure and a significant number where HPV test is requested 'to aid management'. For this latter category there is pressure to use additional molecular and other techniques from colposcopy staff, and these are often undertaken. It was acknowledged that in some cases this was an 'off label' use, but all tests have been internally validated in accordance with ISO quality management processes.

HPV testing can be undertaken with the Roche Cobas system or the Hologic Aptima system. At the current time, the Roche system is being used because this includes an internal control, though it should be noted that the current backlog means that this is not in line with the systems' FDA approval. This is acknowledged, but there is an internal validation policy in place which it is felt allows the system to be used.

Staff at CWIUH are very committed to use of an evidence base in cervical screening, and indeed through various research projects are attempting to provide that evidence. There is a tendency to push somewhat ahead of current agreed standards and rely on internal validation processes for more novel approaches.

Data management is very robust. The laboratory uses the Cyres system, which is a laboratory data analysis package. They have a suite of standard enquiries specified by CervicalCheck and installed by the system developer, and they are also able to customise enquiries. There is good reporting of data and of note, this laboratory independently decided to produce data excluding samples taken from colposcopy, in order to benchmark against UK laboratory results.

There is a culture of audit: for example, an excellent audit of inadequate rate by individual sample takers was undertaken in 2017.

This laboratory is fully aware of the specification of reporting using the Bethesda System. There is strong compliance in some areas, for example using the cut off of 5,000 cells for adequacy. Despite this, the Inadequate rate is quite high (3.3% in 2017) and staff attribute this to an older cohort of women being screened. There has been no discussion from CervicalCheck about possible reasons for this or actions to be taken.

TBS is, however, challenged by this laboratory, particularly in the area of ASC-H (category P3b), which is almost never used. Staff are aware of this. They agree with the UK approach, and have the view that this categorisation has little meaning in an

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HPV triage setting. They choose to assign most possible cases to the P5 category of HSIL. It is noted that this has had no detrimental effect on Positive Predictive value.

In general, staff at this laboratory feel that the quality of cytology reporting they see from other laboratories is good. Differences of opinion remain over the classification of glandular abnormalities. CWIUH review cases from their linked colposcopy units including referral cytology, which may originally have been reported in other laboratories. These slides are requested from the original reporting laboratories and reviewed by CWIUH consultants and if necessary a revised report is issued. This is in the patient records and in records held by colposcopy, but the reports have not been collated by the laboratory.

Overall, the Scoping Inquiry was impressed that CWIUH is extremely committed to the delivery of cervical screening for the Irish programme and has as its focus the development of new and better ways to screen, and the staff skills and qualifications for a new world of cervical cancer prevention based on molecular technologies. This is a world-leading research unit in this respect. A strong ethos of collaborative working, with all parties including other cytology providers, was apparent.

6.9 Quality Assurance Visits

6.9.1 *Principal Quality Assurance Visits*

Two rounds of Quality Assurance (QA) visits were carried out by CervicalCheck, in 2011 and 2014. This constituted five visits in total, to MLP (Sandyford, Dublin), TDL (London), CPL (Austin, Texas), Quest (New Jersey), and CWIUH (Dublin).

All the visits were carried out by a team which included a consultant cytopathologist based in the NHS in England.

The 2011 visit reports were headed 'North West Quality Assurance Reference Centre'³⁶, at which the UK-based consultant cytopathologist was at that time in a senior role. By 2014, the consultant cytopathologist was no longer in that post and the title had been removed from the QA visit report for that year; however, the format is the same throughout all the reports.

There is no indication as to what the ownership, commissioning or governance of these reports is. They do not include the CervicalCheck or NCSS heading or logo.

The format used does not relate to the standards published by CervicalCheck. In general, the reports contain a number of personal views and recommendations which are not aligned to standards. However, it should be noted that these reporting problems were also identified in the English screening programmes at this time, and Public Health England has subsequently made great efforts to standardise QA visit

³⁶

The then North West Cervical Screening Quality Assurance Reference Centre is now part of Public Health England – see <http://www.nwcsqarc.org.uk/>

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reports relating to NHS cervical screening. Up to 2014, these reports would not have been unusual in their content.

The Scoping Inquiry notes following key points in the reports:

CPL QA Report 2011

- A number of apparently reasonable recommendations were made by the QA visit team;
- It is clear that no assurance was given by CPL on a number of standards;
- The response to the report from CPL did not address all concerns, e.g. the rate of reporting of ASCUS;
- The HSE responded appropriately, to the effect that the response from CPL was inadequate, but there is no record of what happened subsequently.

MLP QA Report 2014

- The report contains a recommendation that consultants should report negative cytology. No reference or standard is given and this is not normal practice. It appears to be a personal view of the author. If implemented, this would have had significant operational impact, which was not considered.
- Also of note, there is a mention of the cervical cancer audit as a technical and educational process. There is no mention of recording the results of the audit;
- As part of the QA visit, a number of slides were reviewed by the visiting team. They identified a consistent error where one of the pathologists, named in the report, classified changes which should have been LSIL as ASCUS. Recommendations are made about retraining, which were subsequently undertaken, but no mention is made of any supplementary report or responsibility for reviewing the management of women whose diagnoses should have been altered. The change from ASCUS to LSIL will not make a management difference in many cases, but it will in some cases;
- The individual concerned was at a very senior level within the organisation. No consideration appears to have been made of any wider impact, such as on training of other staff, of this error. These views were not communicated to the people involved so that any response could be noted. This information should be read in that context and any views expressed are, for these reasons, tentative only, due to the inability of the Inquiry to test the original report or to invite and consider any response.

Quest QA Report 2011

- A slide review was undertaken which indicated a significant proportion of slides had been classified as ASCUS, ASCH or AGUS, but were felt on review to be negative;

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- The report makes no comment about responsibility for issuing supplementary reports. It appears likely that these diagnoses were not formally reviewed and documented, and that patient management was not amended;
- There is a comment that this policy was 'safe, but increased the colposcopy burden'.

Quest QA Report 2014

- This report contains extensive commentary on HPV testing, which had been introduced for triage;
- There is an interesting section on audit of previous cytology, when cytology in 2013 was diagnosed as HSIL+. It states that 2,675 cases had HSIL+ of which a previous negative was identified in 1,224. An educational review was carried out on 222, of which 39 cases were reclassified. This was quoted as a 3.19% rate of reclassification. This figure, in the view of the Scoping Inquiry, is misleading. It is derived from 39/1224. However, only 222 of these cases were reviewed (reason not given) so the percentage should be $39/222 = 17.6\%$. No comment is made whether this figure is high, but clearly 17.6% is more worrying than 3.19%. There are no figures to compare this to international practice. As these women now had a positive cytology diagnosis, there would be no impact on their current management. It is assumed that some of them now had invasive cervical cancer and therefore would appear in the cervical cancer audit.

CWUHU QA Report 2014

- At this time, the screening service at the Hospital was relatively new;
- The report notes that the hospital was unable to provide all QA data, including screener sensitivity monitoring, individual PPV. This was subsequently rectified with the installation of new software.

6.9.2 Further QA Visits

No further round of QA visits to any location involved in the CervicalCheck programme has been undertaken since 2014. This is surprising and not in line with best international practice which would suggest visits every three years unless there was a reason to actively change the schedule. Any decisions moving QA visit schedules either forwards or back should have been discussed and minuted at a high level within the organisation.

The Scoping Inquiry believes that the early rounds of QA visits were limited in their governance, design and effectiveness. Opportunities were missed to develop the QA process, and the absence of a further QA visit to all reporting sites by 2017 has resulted in a failure to assure aspects of quality of provision.

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6.10 Cervical Screening Data

6.10.1 Overview

Presentation and analysis of data is a key feature of cervical screening quality assurance. The Scoping Inquiry has not been able to identify evidence that a standard data set was published or analysed, or any source documenting a systematic critical review of data and decisions on action to be taken.

Various fragmentary sources of data have been identified. The Inquiry has focused on:

1. Whole programme population based data
 - a. Reporting rates for cytology categories
 - b. Measures of correlation between cytology and final outcome
2. Comparisons between providers
3. Internal quality monitoring

Details of data retrieved and a commentary and explanation of interpretation are included in Appendix 1.

6.10.2 Comments on Cervical Screening Data

The disappointing quality of records and the inability to review sequential monitoring documentation prevented full analysis by the Scoping Inquiry.

There is very little evidence of critical discussion, further investigation and documentation of actions as a result of identification of unusual data findings within laboratories and CervicalCheck

There is evidence that practice has changed in relation to the reporting of some categories of abnormality, almost certainly as a result of feedback and intervention by CervicalCheck. However, there are examples of occurrences, including a high rate of reporting of low grade abnormalities, where there was a failure by CervicalCheck to recognise that this would have a significant adverse impact on a large number of women.

Specificity of cytology is consistent and compares adequately with international practice. Specificity may in fact be higher but there is a lack of ascertainment of all histology results, which is unacceptable.

There are differences in detection rates between laboratories but the significance is unclear. Reasons for this include:

- The data includes samples from colposcopy. Thus, abnormality rates are highly influenced by the number of colposcopy samples and this could be very variable, and would also be sensitive to colposcopy practices. Up to 10% of

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samples appear to come from colposcopy, although reasons for this are unclear. There should be no indication for repeating a recent cytology sample. Tests of cure samples could be undertaken at colposcopy or in the community.

- There has been no analysis of the factors likely to lead to higher true incidence of abnormalities, such as age profile, rural vs urban and socioeconomic status of women assigned to each provider.
- Not all laboratories have used the same definition for grades of abnormality.

Internal quality monitoring has been fully reported to CervicalCheck. However, with one provider screener sensitivity appears implausibly high. This requires further investigation.

6.11 Analysis

The provision of cytology services to CervicalCheck is by a number of laboratories in different regulatory jurisdictions. Currently laboratories are used in the Republic of Ireland (public and private), the US and England. Discussions are ongoing between the HSE and Sonic regarding the possible use of a laboratory in Australia.

Now and in the past, there is/has been insufficient understanding from CervicalCheck that work is being outsourced to laboratories other than the primary recipient, and only incomplete ascertainment of the quality parameters operating in the outsourced sites has been made. The Scoping Inquiry was satisfied with quality management processes in the current laboratory sites in Quest, MLP, TDL, CWIUH, and at the former provider CPL in Austin. The quality management, governance, regulatory, and operational management aspects of the other Sonic Healthcare sites in the US (San Antonio, Victoria, Las Vegas, Honolulu and Orlando) will be the subject of a supplementary report to be prepared by the Scoping Inquiry.

All of the laboratories visited by the Scoping Inquiry are meeting the regulatory requirements current in their own country. There is abundant research evidence that screening sensitivity varies in different countries.³⁷ As far as can be ascertained, all the laboratories have performance which is acceptable in their country.

Screening programmes require documented specification for laboratory quality management and detailed programme standards relating to both laboratory process and outcome measures. These are required in order to implement a more reliable quality assurance process. While workload and productivity appear well managed across providers, other quality indicators have been less satisfactorily managed.

There is variation in reporting practices between the four current providers, particularly with regard to difference between the UK system of classification (BSCC)

³⁷

Koliopoulos G, Nyaga VN, Santesso N, Bryant A, Martin-Hirsch PP, Mustafa RA, Schünemann H, Paraskevaidis E, Arbyn M. Cytology versus HPV testing for cervical cancer screening in the general population. The Cochrane Library. 2017 Jan 1.

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and the TBS classification used in the USA and elsewhere. It is essential that all providers use the same classification in order to allow comparison of results.

Data collection and analysis is insufficient to monitor and take action on performance differences which might require action. When quality issues, or potential quality issues, have been identified by CervicalCheck, there is insufficient evidence of attempts to confirm resolution, acceptance that resolution has occurred, or documentation of a risk management approach to be taken if resolution is not possible.

The Scoping Inquiry considers there is no reason, on quality grounds, why the existing contracts for laboratory services should not continue until the new HPV testing regime has been introduced.

6.12 Recommendations

- 9) CervicalCheck should revise its programme standards to clarify what is mandatory, and to clarify the level of reliance on external accreditation processes. This is particularly important in respect of laboratory service providers in other jurisdictions.
- 10) As a priority all providers should fully implement a single agreed terminology for the reporting of results and ensure that criteria for defining the different grades of abnormality are consistently applied.
- 11) Based on revised programme standards, a specification for a new and more robust quality assurance procedure should be documented and form part of the contract for services with cytology providers.
- 12) CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.
- 13) CervicalCheck should document which organisation (e.g. CervicalCheck, HSE, Providers) has responsibility for pursuing issues of continued non-compliance and the consequences thereof. An advisory group of cytopathologists and other laboratory based staff should be established to advise on this process, and this should include input from those who work for non-State providers.
- 14) CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.
- 15) In order to obtain comparable data CervicalCheck should amend data specifications to exclude samples taken from colposcopy, and analyse and publish all performance statistics on samples taken in primary care, or equivalent, only.
- 16) When this change to comparable data is made further epidemiological investigation is required to establish whether the differential rates of abnormality persist and, if so, to what extent they can be attributed to underlying population differences.

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- 17) The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.
- 18) The different inadequate rates are not a cause for immediate concern. The Scoping Inquiry recommends that the findings of the English health technology assessment (HTA) study³⁸ referenced in Appendix 1 are implemented across all providers to try to obtain more consistency.

³⁸ Kitchener HC, Gittins M, Desai M, Smith JH, Cook G, Roberts C, Turnbull L. A study of cellular counting to determine minimum thresholds for adequacy for liquid-based cervical cytology using a survey and counting protocol. [Health Technol Assess](#). 2015 Mar;19(22):i-xix, 1-64. doi: 10.3310/hta19220.

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7 Procurement of Laboratory Services

7.1 Introduction

The NSS began the first of a series of public competitions in 2007 for provision of cervical cytology laboratory (Liquid-Based Cytology – ThinPrep™) screening services. Since then, and as reported in Section 5 above, a number of private sector laboratory companies have been engaged to deliver these services:

- Quest Diagnostics, Inc. of Trenton, New Jersey, USA;
- Laboratories owned by Sonic Healthcare, a global healthcare company whose headquarters are in Sydney, Australia, and which includes:
 - Clinical Pathology Laboratories (CPL) of Austin, Texas, USA;
 - MedLab Pathology Ltd. (MLP) of Sandyford, Dublin, Ireland;
 - The Doctors Laboratory (TDL) of London, UK.

In addition, cytology testing is also undertaken for CervicalCheck by the Coombe Women & Infants University Hospital, Dublin. This service is based on a Memorandum of Understanding between the HSE / NSS and CWIUH, and is outside the public procurement competitions involving the private sector providers.

7.2 Procurement Timelines

The following table is a timeline of the key Request for Proposals (RFP) competitions for cervical cytology screening services.

Year	Competition	Outcome
2008	Initial competition for screening services	Quest Diagnostics Inc. was awarded a contract for provision of services commencing in August 2008 for two years with an option for a two-year extension.
2010	Second competition	Sonic Healthcare (Ireland) Ltd. won 50% of the competition for provision of the service by its sister firm Clinical Pathology Laboratories Inc. (both part of Sonic Healthcare). Quest Diagnostics Inc.'s original contract was extended to 2012 for the remaining 50% of the service.
2012	Multi-vendor framework Competition	Quest Diagnostics Inc. was awarded a new two-year contract with an optional one-year extension to 2015. MedLab Pathology (Ireland) Ltd. was awarded a two-year contract with an optional one-year extension to 2015. Both of these providers were awarded framework contracts as well.
2014	Mini-competition 1	Both framework members' contracts were extended as the most economically advantageous option, each by two years to 2016, with further options to extend in 2016.

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Year	Competition	Outcome
2016	Mini-Competition 2	MedLab Pathology (Ireland) Ltd. reduced its price and received a new contract extension. Quest Diagnostics did not, and also received a contract.
2017	Contract Extensions	Contracts were extended past their duration, pending a new procurement competition in 2018.

7.3 Assessment of Approaches to Procurement by the NSS

7.3.1 Limitations of Analysis

Of fundamental impact on the Scoping Inquiry analysis has been the fact that much of the original proposal material was destroyed in 2017 by the NSS, in line with HSE policy for document retention and disposal, and as a consequence some of the key material relating to the CervicalCheck tender competitions was not available to the Scoping Inquiry. The footprint of the proposals does exist in the form of tender evaluation spreadsheets and other notes. However, important original documentation such as original proposals from early procurement competitions no longer exists, and it is therefore difficult to reach informed conclusions on some aspects of those processes.

7.3.2 Overall Assessment

Despite the limitations referred to above, the Scoping Inquiry has analysed all of the various procurement competitions run by the NSS over the lifetime of the CervicalCheck programme, and has identified a range of weaknesses in the overall procurement approach which are discussed in the following paragraphs. These relate to aspects of competition where things could have been done better, or where greater compliance with procurement best practice could have been achieved. At no stage have any procurement irregularities been identified, nor is it the conclusion of the Scoping Inquiry that the wrong tenders were judged to be successful, or that any contract for the provision of cytology services should not have been awarded.

It is likely that the best proposals were received from the successful bidders. Without sight of the proposals themselves, it is not possible to determine whether the successful proposals effectively met the service delivery requirements or whether they were merely superior to unsuccessful proposals.

The HSE has supplied the Scoping Inquiry with a large body of documents pertaining to procurement processes (1,083 out of a total of 5,494), including lengthy and complex contractual material. Some of these documents only became fully available to the Scoping Inquiry in July, and documents relating to procurement were being received and analysed by the Scoping Inquiry up to the 5th September. As a consequence, more work will be required in order to understand fully the issues associated with each of the procurement competitions, including further interviews with NSS staff involved at the time, and engagement with organisations which

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tendered for the provision of cytology services at different stages (including those whose tenders were unsuccessful).

On that basis, the following paragraphs provide a high level assessment of the issues pertaining to each procurement exercise, based on the information provided to the Scoping Inquiry and within the limitations referred to above.

7.3.3 Initial Request for Proposals (RFP) – 2008

The initial invitation for tenders at the beginning of the programme resulted in the award of the contract to Quest Diagnostics (described in Section 6).

The RFP documentation was developed by a third party in consultation with CervicalCheck and NSS staff. While legally sufficient, the Scoping Inquiry believes that the RFP underspecifies detail in respect of expected service levels and quality. The documentation appears to lack a sufficiently expert scientific articulation of CervicalCheck's requirements which is surprising for a service of this scale and national significance.

Gaps in the areas of specification of service levels resulted in bidders having unusual latitude in the development of their proposed solutions.

There is no evidence that the evaluation of the bids included consultation with an experienced external evaluator or auditor, nor with the originator of the RFP documentation, which would not be considered normal in a competition such as this.

20% of the proposal's scoring was based on the fee proposal, and a combination of interview and the documented submission was used to inform the decision. While the reasons provided in debriefs to unsuccessful candidates are sound, the absence of original submitted proposal documentation means that there is no way of determining whether or not the successful tender was in fact a fit-for-purpose proposal.

7.3.4 2010 Competition

The 2010 competition resulted in the award of 50% of the contracted service to Sonic Healthcare (Ireland) Ltd., for provision of the service by its sister firm Clinical Pathology Laboratories, Inc. (CPL; both part of Sonic Healthcare). Quest Diagnostics' contract was extended to 2012 for the remaining 50% of the service.

This competition was an improvement in most respects over the first competition. CervicalCheck's service level requirements were more clearly articulated in the documentation, which was developed in-house, and significantly improved. It is evident that by comparison there was a more considered understanding of what was being procured. Service and quality remain underspecified in the Request for Proposals (RFP), however.

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There appears to have been a strong belief that the incumbent service provider (Quest) could adapt their provision to meet more granular requirements, despite not being successful in the actual competition.

While the NSS appears to have had increased capacity to evaluate tenders (more experience and expertise, and greater consultation), the Scoping Inquiry was unable to find records of the way in which the efficacy of tenderers' quality measures and procedures were determined in evaluation.

Since the 2010 RFP was constructed differently to the 2008 competition, and that specific quality requirements had been introduced, the net effect of the outcome of the competition was two providers offering the same service under different terms – Quest under the terms of the 2008 RFP, and CPL under new 2010 terms.

7.3.5 2012 Multi-Vendor Framework Competition

A framework competition is a procurement process whereby a number of suppliers compete for inclusion in a restricted list of suppliers who are then invited to tender for specific contracts via 'mini-competitions'. Frameworks are an accepted aspect of procurement good practice and are used extensively by the Office of Government Procurement, the HSE and other public bodies in Ireland.

The 2012 competition, which took place after Cervical Check had become part of the HSE, resulted in framework agreements and a new contract for Quest Diagnostics and a contract for MLP (as described in Section 6). Both contracts were for two years with optional two-year extensions.

Once again, the RFP documentation was developed internally and was broadly similar to the 2010 competition, although informed by the HSE's Tender Competition Rules.

The Scoping Inquiry found that as with previous competitions, quality and service delivery controls were still under-specified in the RFP documentation, which also features a significant and increased emphasis on the scoring of the fee proposal. The Scoping Inquiry found that cost considerations became more prominent over time – in 2008, price was weighted at 20% of the overall tender evaluation, but by 2012 this had risen to 40%.

The evaluation was carried out competently, notwithstanding the persistent issues with the scoring and under-specification of service delivery of controls, as set out above.

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7.3.6 2014 and 2016 Mini-Competitions

There were two mini-competitions run in April 2014 and April 2016 within the framework described above.

Having already completed a variety of qualification criteria, providers were invited to supply responses, evaluated under three criteria:

- Suitability to pursue professional activity (pass/fail);
- Ultimate cost (80%);
- Value added services (20%).

Although the NSS ran these mini-competitions off the framework, no tender was deemed successful and no new contract was agreed. Instead, extensions for the framework members were agreed in 2014 as the most economically advantageous outcome.

The 2016 mini-competition had the same outcome, although one of the two external providers offered a reduced fee proposal, which resulted in savings obtained from this provider.

The suitability of the evaluation criteria and the conduct of the mini-competitions within this framework should be subjected to further analysis, to be covered in a supplementary report to the Minister.

7.3.7 Extension of Contracts in 2017

In June 2017, extension of contract notices were sent to Quest Diagnostics Inc. and MedLab Pathology Ltd. with unchanged contract terms.

Consideration of the documentation available to the Scoping Inquiry did not reveal how the NSS ended up in a situation where it was extending this contract beyond its prescribed period. This topic, as with much of CervicalCheck's procurement history should be subject to further investigation and analysis, and should be dealt with in a supplementary report.

7.4 Analysis

7.4.1 Key Issues

This section discusses the main issues with the procurement process for CervicalCheck from 2008 onwards:

- There appears to be an over-emphasis on obtaining the lowest cost from suppliers without equivalent emphasis on other quality and service-level measures. The RFP documentation for each primary tender consistently underspecified quality and service level expectations.

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- There was (and is) no comprehensive and measurable suite of service delivery metrics to ensure that the bidders delivered across the breadth of the contract. No contract governance controls appear to have been defined within the tender process and as a result there is limited ability to govern the service during delivery.
- The approach to evaluation may have the consequence of making it more difficult for new prospective providers to enter into the procurement process, insofar as this is documented. This may be one potential cause of what appears to be an effective duopoly.
- There has been over-reliance on contract extensions. No documentation has been made available to the Scoping Inquiry which suggests that the NSS has attempted to test the wider supply market (outside of the incumbent suppliers) since 2012.
- From what the Scoping Inquiry can determine to date, no efforts appear to have been made to learn from the service delivery experience and make improvements to the RFP since 2012. Since then, the documentary evidence suggests that the NSS considered the cost of the service to be the most significant, or even the determining factor, in evaluating proposals and extending contracts.

It is important to note however, that the Scoping Inquiry found no evidence to suggest that at any time the NSS was less than fair in its evaluation of tender submissions or that each competition did not endeavour to select the best value for money for CervicalCheck.

7.4.2 Conformity with Procurement Rules and Effective Practice

The NSS appears to have complied with procurement law and regulation, but equally it appears to have been less concerned with what was involved in procuring a good service.

Service levels were not specified at all in the first RFP, and there was limited understanding of the service being procured. This did improve subsequently, but remained below a level that the Scoping Inquiry would considered effective by international standards.

7.4.3 Use of Contract Extensions

In order that a contract is managed effectively, the procurement function must plan for contract expiry. This includes determining how to get the best value for money, and, as a result, extending or renewing the existing contract, or going out to tender again.

The NSS last tested the market in 2012 and since then has engaged in a variety of mini-tenders and contract extensions. Planned developments in the delivery of the CervicalCheck service (i.e. the move to HPV screening) appear to have been a

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motivating factor in the decision not to test the market at points of contract expiry. There is no evidence of what criteria informed this decision. Whether or not this is a reasonable determination should be the subject of further investigation and documented in a supplementary report. However, it prompts the question that this approach may have diminished the ability of other suppliers to compete for this contract (or its future variants).

A well-functioning procurement process follows the following basic principles in determining whether to extend a contract:

Area	Description
Supplier Performance	<ul style="list-style-type: none"> Has the supplier met expectations and performed well against key performance indicators? Is the contractor satisfied with the supplier's service?
Demand requirements	<ul style="list-style-type: none"> Is the contract still fit for purpose? Have the service requirements changed?
Market Analysis	<ul style="list-style-type: none"> Are there new market suppliers for the goods and services? Can you obtain better products for a better price? Has there been any innovation which means that other goods/services are now available that better meet your needs? Are conditions favourable for going back to the market? Could you obtain a more competitive price or better result if you delay going back to market?
Procurement Arrangements	<ul style="list-style-type: none"> Are there any procurement arrangements or activities planned or in place (for example, common use arrangements) that might impact on the extension or renewal?

It is considered effective practice to produce a contract review report at frequent intervals during the lifetime of high-value contracts and contract extensions such as these. This ensures that demand requirements, supplier performance, risk assessment, stakeholder satisfaction, and pricing are benchmarked against competition. The Scoping Inquiry was provided with no such report in respect of any extension.

Another contract extension is being negotiated at present – albeit for a short period (less than one year) to facilitate CervicalCheck to transition to an HPV-screening model. The NSS has now moved far beyond the terms of 2012 RFP, but the

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approach is considered prudent, due to the short timescale and likely market interest in providing for the outgoing CervicalCheck model.

Normally, where major changes to a service model are not planned, there is no specific rule on how many times a contract may be extended, but it is normal practice to test the market at the end of the contract period.

7.4.4 Contract Compliance (Post Award)

From the documentation available to the Scoping Inquiry, the only measure of contract compliance that the NSS concerned itself with directly was the turnaround time on tests; all other quality assurance measures were adjudged based on third party accreditation of laboratory facilities and regulatory compliance. It is a failing of the procurement process that there was not a comprehensive and measurable suite of service delivery metrics to ensure that the bidders delivered across the breadth of the contract.

7.4.5 External Reviews

The Scoping Inquiry was provided with documented external HSE reviews of the primary tender competitions, concluded in May 2018. It has not been possible to usefully determine what the scope of these reviews was from the available documentation. They appear perfunctory and do not comment on the efficacy of the NSS procurement processes.

7.4.6 Management of Procurement

It would be expected that public competition and contracting on this scale would have been accompanied by significant HSE oversight and risk management. The Scoping Inquiry has seen limited evidence of such oversight (as discussed in Section 5). This could be an issue for concern to be reviewed and reported on in a supplementary report.

7.4.7 Tender Award Criteria

The following table outlines the evolution of the tender award criteria for the three primary tender competitions.

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Tender Award Criteria	Scores		
	2008	2010	2012
Fee Proposal	20%	35%	40%
Understanding of Requirements/Execution Methodology 2010	25%	55%	55%
Turnaround Time to Process a Smear Sample from the Verification Date to the Response Date (as defined in Schedule 1) (max 10 Working Days)	20%	10%	
Available Capacity, Resources, and Readiness to Commence Provision of Services	20%		
Relevant Experience	15%		
Value added Services			5%
Total	100%	100%	100%

As outlined above, there was a need for greater specificity and weighting in the award to specific quality and service metrics. As can be seen however, the weighting attached to these categories decreases while the weighting attached to the fee proposal increases through each iteration.

7.5 Recommendations

- 19) Winning proposals should be appended to the relevant contract and not destroyed until at least one year following the termination of the contract (and any extension thereof).
- 20) A system should be put in place for proactive contract governance in order to safeguard the future of the service and the relationship of the service with the market place.
- 21) Procurement processes for external laboratory services should be designed to test the market at reasonable intervals (e.g. every four years), to ensure that CervicalCheck does not become overly reliant on a small number of incumbent suppliers, and to ensure that innovative approaches and added value can be formally captured within the procurement process.
- 22) CervicalCheck should ensure that its procurement approach maintains a balanced focus on qualitative factors, supplier experience, and innovation, alongside cost considerations.
- 23) CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.
- 24) External professional assistance should be sought in the construction of any future RFP, and the evaluation of proposals in order to ensure that best practices developed across the public sector since 2012 are incorporated into key areas such as development of RFP documents, supplier briefings, construction of award criteria, construction of evaluation panels, establishment of governance and continuous improvement programmes, etc.

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- 25) Assurances should be sought with respect to the capability to deliver the service as specified and without material change. Where change is possible, robust change management procedures, which include approval by the procuring authority, should be defined.

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8 Auditing Cervical Screening

8.1 Background

The principle of audit, in general terms, is to monitor the effectiveness of a health intervention, to identify areas of good practice and to make recommendations for improvements. The preferred approach is based on an audit cycle, whereby changes are made on foot of the recommendations, the standards revised if necessary, and the process of auditing resumes at the appropriate time.

Cervical screening is a complex, multidisciplinary process affecting a large population. The intention to audit is commendable. A properly designed audit should cover the whole programme pathway, and not simply focus on the primary screening test, which is cervical cytology. Recommendations arising from the audit could cover changes as diverse as, for example, colposcopy, administrative procedures and population database management.

Cervical cytology has been very thoroughly evaluated over many years but there has never been a randomised controlled study of cervical cytology for the prevention of cervical cancer and such a trial would now be impossible and unethical to carry out because it would place some women at risk. In the absence of such evidence from trials, information generated by audit can be a valuable contribution to the science of screening and the design of programmes.

Cervical cytology interpretation is a clinical interpretative skill, rather than relying on a numerical, analytic test. As such, it is highly dependent on a skilled workforce, and one of the key purposes of the cytology component of the audit would always be to identify cases where something could have been done better and to share the learning experience from these cases.

Because cases can only be included in the audit after diagnosis of cervical cancer, many of the slides reviewed will be several years old. The original staff may have left, technology may have changed, and training and quality assurance may have improved. Therefore, any findings from the audit may well be of limited use in managing current quality standards. **For this reason, the overarching aim of all such audits in relation to cytology review has been educational.** An influential and structured protocol for cervical cancer audit was first published in England in 2006.³⁹

“I would also hope that your report strongly endorses the general concept of audit reviews.”

³⁹

Audit of Invasive Cervical Cancers. NHSCSP Publication No 28. December 2006.

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8.2 The CervicalCheck Audit

Implementation of the audit by CervicalCheck has been difficult to follow. There have been a large number of iterations of the audit protocol, seven in total, but most have not been published. The first four versions of the protocol were titled, *Process for the review of incident cases of cervical cancer following the introduction of a national cervical screening programme*. The fifth version became active in February 2016 which coincided with the dispatch of the first set of open disclosure letters and its title was altered to *Clinical audit process for incident cases of invasive cervical cancer*. It was not until this fifth version of the protocol that an aim for the audit was actually defined.

*The aim of the audit process is to examine individual cancer cases in a systematic and detailed way. The audit is conducted with the goal of learning in order to underpin that continuous improvement of the programme.*⁴⁰

It is notable that, particularly in its earlier phases, the protocols were brief, and throughout there was minimal consultation with clinicians in designing the audit. Indeed, the lead colposcopists were very clear in their view to the Scoping Inquiry that they had no involvement, and felt that they should have. Significant changes to the audit process were made at times. For example, at the start, if results of review slides came back and there was a changed interpretation to a low grade abnormality, that was accepted. If, on the other hand, the review result was that there was a high grade abnormality, the slide was sent for external review. In 2013 the process followed was reversed, and it was low grade abnormalities that went to external review and high grade changes were accepted.

It appears that the first cases were logged in 2011 and the earliest case which underwent cytology review was sent to the laboratory in 2012. There was minimal instruction to the laboratories on how to undertake the review of slides, though it is clear that it was never expected to exactly replicate routine screening practice.

Governance of the audit seems to have been weak. It was discussed in occasional meetings which were irregular and not well recorded. It appears that many of the decisions were made by a small number of senior staff at CervicalCheck in an informal way. Without interviewing and inviting responses from each of those involved, it is impossible to reach a firm conclusion on the methods employed and the Inquiry can comment only on the records available to it.

Audit results have never been published. For a long period, data in documentation associated with individual audit cases was not abstracted and collated. Some details of cases sent for review were apparently intermittently collated for discussion within CervicalCheck. Notes of a CervicalCheck Cancer Review Process meeting involving

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CervicalCheck. Clinical audit process for incident cases of invasive cervical cancer. CS/PUB/PM-10 Rev 5.

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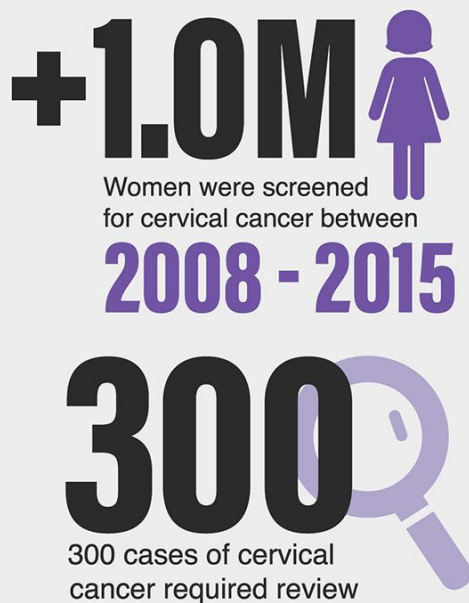
senior staff from the NSS and CervicalCheck held on 25th August 2015 give a good update on progress at that stage.

According to these notes, over one million women had been screened in the seven years since September 2008 and 1,067 cases of cervical cancers had come to the attention of CervicalCheck by March 2015. The internal team of three CervicalCheck staff who comprised the Cancer Review Team reviewed each individual cervical cancer case at scheduled Review Meetings. They decided that of the 1,067 cases reported, a review was not appropriate in 767. However, 300 did require further review. The focus for reviews was decided by the Team and ranged across five distinct areas of the screening programme. These were:

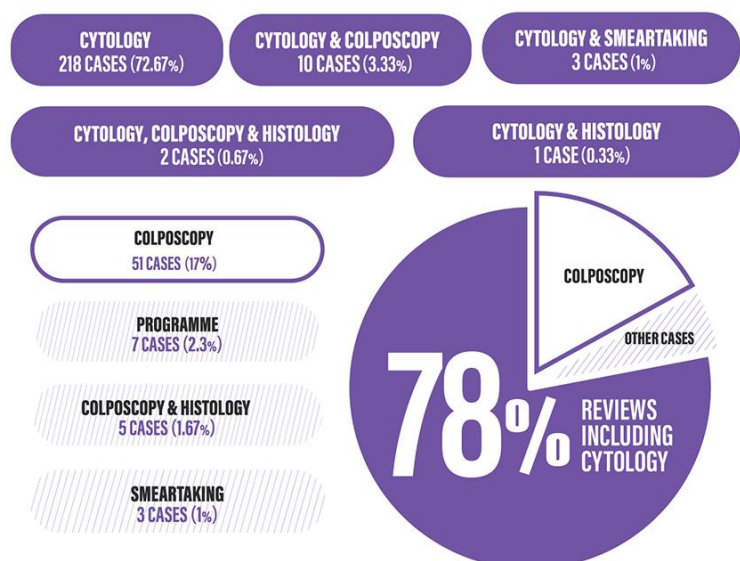
- Cytology
- Colposcopy
- Programme issues
- Histology
- Test-taking

A small proportion (7%) of cases required review in more than one area. The distribution across the areas was, as would be expected, far from even, with 78% of reviews involving cytology.

AREAS OF FOCUS FOR 300 CASES REQUIRING FURTHER REVIEW AS IDENTIFIED BY THE CANCER REVIEW PROCESS 2008-2015



THE AREAS OF FOCUS FOR THE 300 HUNDRED CASES IDENTIFIED AS REQUIRING FURTHER REVIEW WERE AS FOLLOWS:



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At this stage the process being followed by the audit was described as follows:

1. *A cervical cancer case is notified to the Programme*
2. *The woman is identified on CSR⁴¹ and her programme screening history is noted.*
3. *Using the information obtained from her screening history, a category is assigned to each case according to the woman's screening history as described below:*
 - a. *Category 1 no previous cytology*
 - b. *Category 2 previous NAD⁴² routine recall >⁴³ routine recall interval*
 - c. *Category 3 previous NAD routine recall < routine recall interval*
 - d. *Category 4 previous cytology – recommended repeats*
 - e. *Category 5 previous cytology – recommended investigation*
 - f. *Category 6 previous colposcopy*
4. *The case is then assigned a screening classification.*
 NO PREVIOUS SMEARS: ☐ Never invited ☐ Invited but letter returned
☐ Non responder to invite(s) LAPSED ATTENDERS ONLY 1 SMEAR BEFORE DIAGNOSIS: ☐ responded to invite ☐ non responder to invite(s)- opportunistic smear ☐ never invited-opportunistic smear ☐ first response at (x) invitation > 1 SMEAR BEFORE DIAGNOSIS: ☐ screened/ not screened at recommended intervals IF PREVIOUS COLPOSCOPY: ☐ attended/ did not attend at recommended intervals
The category and classification are used to identify cases that require further review e.g. a woman with a previous NAD routine recall (category) with cancer diagnosis within 42 months following the smear test who was screened at recommended interval (classification) and those that do not e.g. a woman with no previous cytology (category) who was invited but did not respond (classification). The classification is also used to identify elements of the programme operation and to inform any future directions to improve the quality of service offered to women.
5. *Each case is logged in the Cancer Review Case Log.*
6. *Cases that require further review are discussed at meetings of the Cancer Review team*
7. *For those cases which require further review, and depending on the category and classification, additional information may be required and one or more of the aspects of a woman's care may be reviewed. The areas that may be reviewed include: cytology, colposcopy, histology, smeartaking and programme. To date, CervicalCheck's Cancer Review has mainly concerned the area of cytology and the process described*

⁴¹ CSR is CervicalCheck's own 'Cervical Screening Register'

⁴² NAD stands for 'No Abnormality Detected'

⁴³ > stands for 'greater than' and < stands for 'less than'

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below is a cytology review of a cancer case. This is by no means the only area that may require review within the process but as all women who take part in the programme have cytology, it is expected that the majority of reviews will have a cytology focus

8. *Initially, an "internal review" is requested of the laboratory where the slide was originally screened. The laboratory will screen the slide again and determine whether the initial result and recommendation are maintained or if they are to be upgraded. If the result and recommendation are upgraded to high grade from the initial findings, the review is complete. If the review confirms the original findings, then the slide is sent for external review. If the external review finds high grade disease when the internal review has found normal or low grade, then a second external review is requested. The outcome of the second external review is final.*
9. *Following the cytology review process, the outcome is fed back to the cytology laboratories for training and educational purposes.*

At the time of this August 2015 meeting, a significant proportion of the cytology reviews had not yet been completed. **But it is clear that the intent was for the audit to be used primarily by the laboratories for educational purposes.**

Further meetings were held on 29th October 2015 and 3rd December 2015, both entitled 'Special meeting of the CervicalCheck Executive Management Team'. These meetings were to discuss 'close out of the audit'. It is clear that other meetings had been held earlier, though not all records are available. On 13th July 2015, a document headed 'CervicalCheck Preventative action CS/PA-464' was issued, highlighting a trend which had been identified. This involved a number of cases where the internal review of cervical tests showed ASC-H and this was increased in severity to HSIL on external review. A senior member of staff in CervicalCheck had in fact written to a doctor at Quest Diagnostics on 10th July 2015 identifying four trends.

1. ASCUS/ASC-H/AGC on original report or internal review are commonly upgraded to HSIL;
2. External reviewers frequently state that cells were misinterpreted;
3. Scanty preparations and microbiopsies are often given as reasons for abnormalities being missed, and there is a suggestion that this should feature in training;
4. There are some cases where external reviewers identify HSIL where both the original and internal review are negative.

This letter asked for four actions to be undertaken and raised concerns about the robustness of the quality control (QC) screening process. An initial reply did not address these issues robustly. A second letter sent on 9th February 2016 to the senior medical director at Quest Diagnostics had essentially the same content. The letter also refers to the next quality audit (QA) visit to be scheduled in 2016, though this visit did not occur. There is a detailed reply from Quest's doctor dated 12th July

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2016. This states that Quest has robust metrics and data was attached to support this view. The letter raises the possibility that the reviewers' prior knowledge of the presence of cervical cancer in the patient was affecting the review.

Subsequently a close-out meeting was held on 28th September 2017 to which all the pathologists involved from the provider laboratories (MLP, CPL, CWIUH, and Quest), and external reviewers, were invited. Some attended in person, others by video link and together they reviewed 24 cases. These consisted of five cases where the cytology had been handled by MLP, four by CPL, and 15 by Quest. Of these 24 cases, in 11 the consensus of the meeting did not agree with the final diagnosis previously recorded in the audit, and in one case no consensus was possible. This illustrates that it is not easy to provide definitive answers in the case of some patients.

8.3 Approach to Audit in Provider Laboratories

8.3.1 Quest

At the time of the Scoping Inquiry visit to Quest, no written protocol was available but the audit was openly and extensively discussed. Quest described how lists of cases to be reviewed were received irregularly from CervicalCheck, usually six to eight cases at a time.

The process for review is that the lead cytopathologist and lead cytotechnologist with responsibility for QA review together try to replicate normal screening times and the approach adopted. No consensus-seeking or panel is operated at this stage. Both of the Quest staff members were very open about this, and the Scoping Inquiry did not form the opinion that they were in any way intending to manipulate the results. The overall understanding of the Quest staff was that it was a purely academic or educational exercise.

The lead cytopathologist expressed a feeling that audits have an upsetting and demoralising effect on the staff. The laboratory submits results of its review to CervicalCheck and receives back a final report with the result of a second, and sometimes third, review. These come back at irregular intervals and the Scoping Inquiry was able to review three sheets of such final reports.

The most recent results sheet had just been returned (July 2018). The final results, in terms of seriousness, were upgraded and downgraded equally, but the Scoping Inquiry looked at three returns and on average there were few upgrades on internal review. Samples were more often upgraded at second and third reviews than not. The lead pathologist expressed the opinion that external reviewers have a tendency to upgrade the designation of slides on review.

All staff present seemed quite remote from policy-making and were certainly under no duress to downgrade. Their stated view is that the slide reviews should replicate normal practice. Findings are shared with screeners or pathologists. If missed

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abnormalities are detected, these are documented and the Scoping Inquiry saw examples of the documentation.

8.3.2 *CPL*

This provider has had very little engagement with the audit of cervical cancer. It had not undertaken any reviews itself. Until recently, the laboratory had supplied, on request from CervicalCheck, any slides for review to MLP and the review had been undertaken by MLP staff in Ireland. As they were at this point (July 2018) not undertaking cytology for the Irish screening service themselves, they seem to have considered any further intervention or actions were not required. Senior staff had not been aware that slides were being sent for review. In more recent months there had been more engagement and the lead cytopathologist had visited the laboratory in Ireland to review the slides, and had participated in a consensus meeting of all internal and external reviewers. No audit results were available to the visiting Scoping Inquiry team.

8.3.3 *MedLab Pathology Ltd*

There was a detailed in-house policy document describing the laboratory's approach to the audit. The two cytopathologists involved in reviews were represented at the consensus meeting. Results of slide reviews are shared with staff. No outcome results were presented to the Scoping Inquiry. There was concern expressed by staff about the way in which disclosure had been handled by CervicalCheck.

8.3.4 *TDL*

This provider has only recently received its first case for review in the audit. It expects to carry out the review in the same way as its NHS cases are dealt with in audits for the English cervical screening programme.

8.3.5 *Coombe Women & Infants University Hospital*

This laboratory has had three cases identified as part of the cervical cancer audit. The Scoping Inquiry was able to review all internal and external records associated with these reviews. There was a clear process for review within the laboratory. Samples were inserted into routine screening if possible, though it was acknowledged that staff might be aware of non-sequential numbering, which would indicate that the samples were not routine. In any case there was a clear intention to replicate normal screening processes as much as possible, but also to take a 'fine tooth comb' to the slides. There was a commitment to learn anything which could be learned from these cases, and to share this learning with all the staff.

Several slides were slightly upgraded on external review and were then revisited by the whole CWIUH team. In some cases, they were still unconvinced about the revised classification. None of these cases was discussed in the consensus session in 2017 and none had been subject to a second external review.

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8.4 Audit Outcomes

A complete presentation of audit outcome data has been impossible to locate. As noted earlier in this section, an audit was carried out in respect of the cases of 300 women with cervical cancer who had been identified for review in 2015. Of these, 234 required review of cytology, either alone or in combination with other aspects of the programme.

The review outcome of 190 of these cases is available. In 120 of these, the review diagnosis would have resulted in referral for a colposcopy. For 62 of these 120 cases, the tests had been performed more than 18 months before the date of diagnosis, and were therefore held to have potentially influenced the management of the women's treatment. Minimal further analysis was presented in these 62 cases, of which 14 were adenocarcinomas and 48 were squamous carcinomas.

There is no analysis of the internal vs. external review results. Because the issues of the cytology review and the impact on patient management were conflated, it is impossible to know how many cases were subject to disagreement on review. The decision to view 18 months as a cut off for clinical impact is undoubtedly flawed, and it is hard to see the logic for this. Considerable tumour progression can occur over this timescale with potential impact on the stage⁴⁴ (and hence morbidity of treatment) and mortality.

It is clear that there was a discussion at the time noting that actions to be taken in the event of abnormalities being missed had not been specified; and there was a lack of certainty about whether this constituted an 'incident'.

A major audit of invasive cervical cancer was undertaken in England and the results were published in 2014.⁴⁵ Not unsurprisingly given the important influence of the 2006 report on cervical cancer audits mentioned above, there are similarities with the Irish auditing system. This report focuses on 8,784 women who had a confirmed diagnosis of cervical cancer between April 2009 and March 2013. In this report it was noted that 59% of cytology slides reviewed showed concordance. This means that the review diagnosis differed from the original in four out every ten tests reviewed. In respect of a smaller subset of tests, 65 negative or inadequate tests within two years of diagnosis were reviewed. Concordance was only 41.5%; 13 (27.5%) were upgraded to low-grade cytology and 20 (30.8%) to moderate or worse. These results clearly show that a very significant alteration in the grading of a test is not something that is unique to the CervicalCheck audit. Unfortunately, it is not possible to directly compare this to the stated outcome data for the Irish audit available to date.

⁴⁴ The stage of cancer describes the size of cancer and whether it has spread from its original area to other areas in the body.

⁴⁵ Sasieni P. Castanon A. NHSCSP audit of invasive cervical cancer: national report 2009-2013. 2014. (https://www.qmul.ac.uk/wolfson/media/wolfson/news-amp-events/nhscsp-audit-invasive-cervical-cancer-Feb_2014.pdf)

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8.5 Response of Quest to Audit Outcomes

As noted above, individual clinical staff at Quest appear to have had no involvement in the company approach to the audit. However, there has been extensive legal activity relating to audit outcomes and disclosure. In its response to CervicalCheck concerns raised in 2016, Quest clearly disagreed strongly with the release of audit information. There is extensive legal correspondence between solicitors acting for Quest and the HSE, and the contractual dispute resolution mechanism was invoked.

8.6 Analysis

The CervicalCheck audit was established with laudable aims but planning, governance and documentation appear to have been inadequate. There was little or no anticipation of the challenges which would arise when cytology (or other) results were reviewed. Participating laboratories were not given a specification of how to undertake cytology reviews and did not do so consistently. Analysis of the results was sporadic and informal. A trend was identified regarding reviews at Quest but no adequate steps appear to have been taken to define whether this represented a genuine issue and, if so, what actions should be taken to resolve it. Insufficient data of acceptable quality has been generated by the CervicalCheck audit to enable the Scoping Inquiry to form an opinion on the overall outcome of the audit, nor to enable comparisons to be made with other audits, such as those in England and Wales.

“It is obviously best practice to check whether you are achieving the best results possible and the furore surrounding the management of this review has the very real potential to deter the HSE from conducting others”.

8.7 Recommendations

- 26) Audits should continue to be an important component of cervical screening as this complies with all good clinical practice. Common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.
- 27) There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services.

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9 Open Disclosure and the HSE

“We should have been told in 2016 when the results came.”

9.1 Background

The development of open disclosure policies in healthcare institutions has taken place over the past 30 years. Its first formulation is attributed to a hospital in Montreal, Canada, in 1987. The initiative is associated with Pat O’Rourke, a woman who was a patient representative on the hospital’s Clinical Ethics Committee. It resulted in the hospital introducing guidelines for disclosing incidents and outlining the principles and procedures to be followed in such cases.⁴⁶

The concept of ‘open disclosure’ and the importance of disclosure to the person(s) affected was incorporated into the HSE’s Incident Management Policy and Procedure published in 2008. It stated:

*Open communication/open disclosure is a vital component of the incident management process. All incidents should be disclosed to persons affected by the Senior Clinician and/or Senior Manager. The person affected by the incident and/or the next of kin, where appropriate, must be kept informed.*⁴⁷

The 2008 policy document on incident management went on to stress the importance of the wellbeing of those ‘affected and/or harmed by the incident’.⁴⁸ The national open disclosure programme commenced in 2010 as a joint initiative between the HSE and the State Claims Agency (SCA).

In 2012, the Health Information and Quality Authority (HIQA), an independent statutory body, was established to drive improvement in Ireland’s health and personal care services and to monitor their quality and safety. It published a landmark document setting out the standards that healthcare providers are expected to achieve and maintain. Standard 3.5 contains a clear statement of what is expected from a service provider:

*Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known, and continue to provide information and support as needed.*⁴⁹

⁴⁶ Peterkin, A. (1990). Guidelines covering disclosure of errors now in place at Montreal hospital. CMAJ: Canadian Medical Association Journal, 142(9), 984.

⁴⁷ HSE Incident Management Policy and Procedure. (2008). p3.

⁴⁸ Ibid.

⁴⁹ HIQA. National Standards for Safer Better Healthcare. (2012). p70

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Meeting the requirements of this HIQA standard was one of the HSE's objectives in bringing forward its subsequent policy document titled '*Open Disclosure: National Policy*'.

The 2008 HSE Incident Management Policy and Procedure was superseded in 2014 by a new HSE policy document titled the '*Safety Incident Management Policy*'. Although this 2014 policy document has a section on open disclosure, it simply refers the reader to another HSE document dedicated to open disclosure that had been published in 2013.

This policy must be read within the context of the HSE / SCA "Open Disclosure: National Guidelines" (2013).⁵⁰

9.2 HSE Policy Document Open Disclosure: National Policy

Along with Ireland, open disclosure has been adopted widely in the US, Canada, Australia and New Zealand, as the correct approach to responding to actual and narrowly avoided incidents of harm occurring to patients in the course of healthcare interventions. Its most comprehensive adoption appears to have been in Australia, where much innovation and research into the topic has taken place. In Australia 'open disclosure' is defined as:

An open discussion with a patient about an incident(s) that resulted in harm to that patient while they were receiving health care. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.⁵¹

The definition used by the HSE in its policy document '*Open Disclosure: National Policy*' in 2013 is very similar:

An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.⁵²

The *Open Disclosure: National Policy* document is 25 pages long and very early in the text it states:

⁵⁰ HSE Safety Incident Management Policy. 2014. p5.

⁵¹ Australian Commission on Safety and Quality in Health Care. Australian Open Disclosure Framework. (2013) ACSQHC, Sydney.

⁵² HSE. Open Disclosure: National Policy. (2013). HSE, Dublin.

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*The service user must be informed in a timely manner of the facts relating to the incident and an apology provided, where appropriate.*⁵³

This would seem to state definitively and clearly that there is no equivocation about the issue. The patient ‘must be informed’; not ‘may be informed’ or ‘should be informed’. It is also worth noting that the paragraph states that the information must be given to the patient in a ‘timely manner’ and accompanied by an apology, ‘where appropriate’.

Yet, only a few paragraphs further on, the policy document states:

*When a clinician makes a decision, based on his/her clinical judgement, not to disclose to the service user that an adverse event has occurred, the rationale for this decision must be clearly documented in the service user’s healthcare record and this decision may need to be reviewed by the clinician at a later date, depending on the circumstances involved.*⁵⁴

There is no explanation given for conferring this discretionary power of ‘clinical judgement’ on health professionals that overrides what seemed, only a few paragraphs earlier, to be a very firm policy of open disclosure. There is not only an absence of an explanation for what appears to be a highly significant modification of the preceding policy statement, but there is no qualification of the authority of clinicians, or the circumstances in which they can make a judgement not to disclose an adverse event to a patient.

Despite this highly significant modification of the concept of open disclosure, the document goes on to state that one of the purposes of the policy is to meet the requirements of the HIQA Standard 3.5 that is mentioned in the first section of this part of the report.

The HSE’s policy document, in Section 7 entitled ‘Guideline’, provides a flowchart that is described as an ‘Open Disclosure Process Algorithm’. A part of the text in the flowchart diverges substantially from the earlier definitive statement that patients ‘must’ be informed. It states that:

*Service users **should** be informed of the occurrence of an adverse event that has resulted in or is expected to result in harm to the patient.*
[my emphasis]

Furthermore, it modifies the statement that disclosure must take place in a timely manner by adding a step to the process whereby consideration should be given to deferring disclosure. It introduces a further step for consideration of whether disclosure might cause additional harm.

⁵³ Ibid Para 2.1 p6.

⁵⁴ Ibid para 2.7 p7.

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Consider if there is a reason to defer disclosure at this time/can disclosure cause additional harm?⁵⁵

These statements add to the general theme of inconsistency in approach that is apparent in the policy document and can surely not assist clinicians and others in developing a clear and coherent approach to the implementation of open disclosure.

“I don’t think it was their decision to make. I am disappointed by this and it makes me so sad that I was let down by something that was set up to help women”.

9.3 Revision and Audit of Open Disclosure: National Policy

Towards the end of the policy document, it states that revision and audit of the policy is necessary ‘to ensure its success’. It places responsibility for revision of the policy, on ‘a 2-yearly basis, or sooner if appropriate’, with the National Advocacy Unit of the HSE.⁵⁶ The document in its opening pages states its revision date as 8/10/2015. However, no revision has taken place. The HSE has informed the Scoping Inquiry that the absence of a process of revision of the policy is due to legislation passing through the Dáil that would have affected disclosure and therefore had to be taken into account in an updating of the policy.

The same section of the policy document states that:

An audit of implementation and compliance at service level is also necessary.

Information provided to the Scoping Inquiry by the HSE shows that an audit was conducted on the implementation of open disclosure in four ‘early adopter’ sites. This was carried out in 2016. The summary report, completed in January 2017, noted that although significant numbers of staff from various disciplines had participated in training programmes about open disclosure, this included ‘a relatively small number of medical staff’.⁵⁷ It is apparent that in three of the four hospitals visited for the audit, concern was voiced about the lack of participation of medical staff in training programmes. The summary report also noted that there was a problem with the consistency of documentation on open disclosure.

In respect of all of the four hospitals classed as ‘early adopters’, a recommendation was made in their individual reports, produced in late 2016, that the senior most accountable person in the hospital must ensure that ‘an evaluation of the effectiveness of the open disclosure training programme is undertaken.’ In response

⁵⁵ Ibid p13.

⁵⁶ Ibid p14.

⁵⁷ HSE Quality Assurance and Verification Division. Audit of National Open Disclosure Policy in selected acute hospitals. (2017).

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to direct questions on this matter, information provided to the Scoping Inquiry by the HSE indicates that only two of the four hospitals have carried out the required evaluation.

As well as recommendations being made in individual reports on each of the four hospitals audited, the summary report makes two more general recommendations:

The National Director of Acute Hospitals must ensure that:

1. *A standardised approach is followed with regard to documenting open disclosure in the healthcare record.*
2. *An evaluation of the effectiveness of the open disclosure training programme is undertaken in acute hospitals.*

In response to a request for information as to what progress has been made in the implementation of the recommendations, the Scoping Inquiry was informed that the approach to documentation of open disclosure, as outlined in the national policy *Guidelines on Communicating with Service Users* discussed further below, was part of the training programmes and workshops on open disclosure run by the HSE. This however did not necessarily ensure that guidelines were followed, as recommended. In respect of the second recommendation, it does not appear that any specific evaluation of the open disclosure training in acute hospitals has yet been carried out. Instead reliance has been placed on existing evaluation activities.

9.4 Guidelines on Communicating with Service Users – Non-Disclosure

Along with the publication of the *Open Disclosure: National Policy* document in October 2013, the HSE and the State Claims Agency published guidelines on the subject of how communications about adverse events should be handled. In the Foreword to the document it states that the guidelines have two purposes:

(a) to establish a standardised approach by healthcare professionals across all of our health and social care services in relation to how we communicate with service users following adverse events and (b) to ensure that communication with service users and staff members involved occurs in a supportive and timely manner.⁵⁸

The guidelines, which run to 124 pages, repeat many of the sentiments and statements contained in the National Policy document. For example, they state:

Service users expect to be informed about any harm they have experienced whatever the reason for it and including an explanation in relation to harm resulting from their disease process.⁵⁹

⁵⁸ HSE - SCA. *Open Disclosure: Communicating with service users and their families following adverse events in healthcare*. 2013. p.vii.

⁵⁹ Ibid p4.

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However, despite the positive statements supportive of open disclosure, the guidelines echo the HSE National Policy document in allowing broad grounds for non-disclosure. Section 6 of the document is titled 'The Open Disclosure Process' and outlines circumstances where non-disclosure may be considered.

6.3.9: Deferred/postponing disclosure

Deferral, either temporary or permanent, may be a consideration in the following circumstances:

- *The service user has died and has no known relatives.*
- *The service user has left the country and cannot be contacted.*
- *The service user refuses open disclosure – may not be ready.*
- *There may be a risk of violence perpetrated/threatened by the service user.*
- ***There is no evidence that the service user will benefit from open disclosure.*** [my emphasis]
- *The service user is extremely ill or dying – disclosure to the nominated next of kin/family member(s)/support person(s) should be considered in these circumstances within the confines of patient confidentiality.⁶⁰*

This paragraph is followed by a note in the text which reads:

NOTE: Only in exceptional circumstances, based on the clinical interests of a service user, is it likely that a service user will not benefit from open disclosure. The reason(s) for non-disclosure should be documented by the clinician in the service user's clinical record and senior management should be informed via internal governance processes. Decisions in relation to disclosure/non-disclosure should include input from the multidisciplinary team. The decision regarding disclosure may need to be revisited later when the service user is less vulnerable.

The fifth bullet pointed reason for non-disclosure highlighted above, is specifically referenced to a study, carried out by a team of academics for The Australian Commission on Safety and Quality in Health Care. It is titled *Evaluation of the Pilot of the National Open Disclosure Standard* and was published in 2007.⁶¹

In that Australian academic study, there is a table presented (table 2.6b) entitled *Instances where Open Disclosure may be (indefinitely) deferred*. It lists instances where they suggest deferral might be appropriate. This list is generally reflected in the HSE list with some modifications. One highly significant modification is in respect to the aforementioned fifth bullet point in the HSE list. In the original Australian paper,

⁶⁰ Ibid p46.

⁶¹ Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. (2007). Final Report: *Evaluation of the Pilot of the National Open Disclosure Standard*. Sydney: University of Technology, Sydney.

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the fifth point describing circumstances where non-disclosure may take place reads: 'It is not evident to staff that the patient (family) will benefit from the Open Disclosure of a "near miss".' Comparing the two, the absence of the words, 'of a "near miss"' ⁶² in the HSE/SCA guidelines is of importance. (Box 1) The removal of those words from the phrase as used by the HSE radically changes its meaning, and opens the way for non-disclosure in the full range of adverse events that patients might suffer.

Australian study	HSE/SCA Guidelines
It is not evident to staff that the patient (family) will benefit from the Open Disclosure of a 'near miss'.	There is no evidence that the service user will benefit from open disclosure.

Figure 9.4-a: Comparison of wording in the original Australian paper and the derivative HSE document on when non-disclosure may take place

The substantial majority of situations where an adverse event occurs and where open disclosure should be appropriate emerge at, or shortly after, the point at which the patient has been involved with the healthcare system. Thus, a look-back exercise such as the retrospective audit carried out by CervicalCheck is an unusual situation and, entirely appropriately, the HSE/SCA guidelines go on to deal with what they term 'retrospective incidents'. ⁶³ The guidelines state:

The probability of harm in conjunction with weighing up ethical obligations is required. An informed clinical decision needs to be made by the Consultant. If the decision made is not to contact the service user(s) the rationale for this decision should be documented in the healthcare record.

Yet again, the guidelines envisage non-disclosure as a real possibility. They also state, quite appropriately, that the rationale for non-disclosure should be documented.

9.5 Analysis

It is clear that there has been a commitment within the senior management structure of the HSE to the concept of open disclosure based on the principle that, when things go wrong with their healthcare, patients have a right to be told. This is entirely appropriate and unsurprising. Policies have been developed that seek to introduce into practice the principles of what is termed 'open disclosure'. Those policies have been promulgated in the health service via training events and workshops. However, the operation of open disclosure as experienced in the field of cervical screening has been significantly flawed in several respects.

⁶² The generally used definition of a 'near miss' is an incident which could have resulted in harm but did not do so, either by chance or timely intervention.

⁶³ HSE/SCA. Open Disclosure: Communicating with service users and their families following adverse events in healthcare. 2013. p70.

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Firstly, and most importantly, HSE policies and the joint HSE/SCA guidelines for the implementation of open disclosure are explicit in leaving a decision on whether to disclose or not, to the unfettered judgement of the clinicians involved. Furthermore, if the doctor decides not to disclose the occurrence and details of an adverse event to a patient, that decision is apparently not subject to any further scrutiny. Most surprisingly, in the HSE/SCA guidelines for communicating with patients about adverse events there is a clause which states that non-disclosure may be appropriate if there is no evidence that the patient would benefit from such disclosure. This is referenced to an Australian study. However, the Australian study makes it abundantly clear that this option is only intended to be considered in cases where there has been a 'near miss', i.e. where no actual harm has occurred. The overall message is contradictory. On the one hand, HSE policies support open disclosure and say it 'must' happen; on the other it makes non-disclosure a distinct option.

Secondly, the implementation of the open disclosure policy by the HSE leaves much to be desired. Despite the limited resources devoted to its implementation, and to the credit of those involved, a great deal of training has been carried out across the country. There has however been no systematic evaluation of the implementation of the policy, or audit of its operation. This is of particular importance because of the reported difficulty in engaging medical staff in the learning process. It is reasonable to expect that medical staff, particularly consultant medical staff, would have been recognised as the key target audience. Even if not recognised initially, this should have been a priority following the four hospital audits carried out in 2016.

9.6 Recommendations

- 28) The HSE's open disclosure policy and HSE/SCA guidelines should be revised as a matter of urgency. The revised policies must reflect the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and, in particular, their right to be informed about any failings in that care process, however and whenever they may arise. The revision process should be overseen by a working party or committee with a minimum of two patient advocates amongst its members.
- 29) The option of a decision not to disclose an error or mishap to a patient must only be available in a very limited number of well-defined and explicit circumstances, such as incapacity. Each and every proposed decision not to disclose must be subject to external scrutiny and this scrutiny process must involve a minimum of two independent patient advocates.
- 30) A detailed implementation programme must be developed that ensures the principles and practice of open disclosure are well understood across the health service. In particular, medical staff must be required, as a condition of employment, to complete training in open disclosure.
- 31) A governance framework for open disclosure must be put in place that includes evaluation and audit.
- 32) An annual report on the operation of open disclosure must be presented in public session to the full Board that is to be appointed to govern the HSE.

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10 Open Disclosure and the Medical Council

10.1 Background

As a consequence of being granted entry to the medical register, and thus having the privilege of practising medicine, medical practitioners are expected to adhere to the principles of medical practice and conduct as set out by their regulatory body, the Medical Council. The Medical Council produces a guide to professional conduct and ethics that doctors are expected to follow.

The current guide, the eighth edition, was produced in 2016 and is titled, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*. In its opening section it states, 'you must exercise your clinical skills and judgement in your patients' interests', and also, 'You should not let your professional actions be influenced by any personal interest'.

10.2 Open Disclosure

These principles of the patient's interest being paramount, and the interests of the doctor being subservient to that, feature prominently in the guide. When it comes to providing information to patients, particularly in the context of things going wrong, the guide supports open and honest communication. It has a specific section titled 'Open disclosure and duty of candour' with two sub-sections. It is quoted here in full.

67.1 Open disclosure is supported within a culture of candour. You have a duty to promote and support this culture and to support colleagues whose actions are investigated following an adverse event. If you are responsible for conducting such investigations, you should make sure they are carried out quickly, recognising that this is a stressful time for all concerned.

67.2 Patients and their families, where appropriate, are entitled to honest, open and prompt communication about adverse events that may have caused them harm. When discussing events with patients and their families, you should:

- *acknowledge that the event happened;*
- *explain how it happened;*
- *apologise, if appropriate; and*
- *assure patients and their families that the cause of the event will be investigated and efforts made to reduce the chance of it happening again.*⁶⁴

64

Comhairle na nDoctúirí Leighis. Guide to Professional Conduct and Ethics for Registered Medical Practitioners. 8th Edition, 2016. p43.

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The first sub-section opens with the statement that ‘Open disclosure is supported within a culture of candour’. However, the rest of the sub-section appears to focus primarily on being supportive towards medical colleagues being investigated in relation to adverse events.

The second sub-section goes on to state, ‘Patients and their families, where appropriate, are entitled to honest, open and prompt communication about adverse events that may have caused them harm’. This statement, which is clearly about open disclosure, appeared for the first time in the 2009 edition of the guide. However, the insertion of ‘where appropriate’ into the text poses a difficulty in that the guide at no point mentions the circumstances in which open disclosure would be deemed by them to be inappropriate.

The importance of informing patients was included in the relevant section of the guide prior to 2009. In the sixth edition, published in 2004 under the title of *A Guide to Ethical Conduct and Behaviour*, it was stated that, ‘In general, doctors should ensure that a patient and family members, subject to patient consent, are as fully informed as possible about matters relating to an illness.’

The word ‘should’ appears twice in the section quoted in full above from the current guide. The word ‘must’ does not appear. In the very first section of the guide there is an explanation of the difference between the use of the words ‘should’ and ‘must’.

*In the guide we use the term ‘you must’ where there is an absolute duty on you to comply with the principle that follows. We use ‘you should’ to describe best practice in most circumstances, accepting that it may not always be practical to follow the principle or that another approach may be appropriate in particular circumstances. You should use your judgement in such cases.*⁶⁵

The wording therefore is such that the individual doctor has no ‘absolute duty’ to follow open disclosure, ill-defined as it is in the guide, and can use their own judgement.

10.3 Analysis

The difficulty with the Medical Council guide quoted above is, firstly, that it is not the interests of patients and families that are at the centre of its approach to open disclosure. It is unfortunate that the initial section appears to be about medical colleagues. Secondly, it is not definitive. The insertion of the undefined phrase ‘where appropriate’ creates uncertainty and can be interpreted in a range of ways. Thirdly, the use of the word ‘should’ can be taken to mean that it is something that is recommended, but remains optional.

⁶⁵

Ibid p7.

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This guidance is not in keeping with a modern patient-centred approach. It isn't even a particularly new concept. As Lamb so correctly put it as far back as 2004:

*The open, honest, and timely disclosure of medical error to patients should be, as Americans say, a “no brainer”. It is ethically, morally, and professionally expected of clinicians.*⁶⁶

The foreword to the guide stresses that it is not a legal code but rather a set of principles that all doctors are expected to ‘follow and adhere to’. It is surely impossible to continue to accept a situation where the principles of open disclosure are not a fundamental and essential part of the professional conduct expected of all registered medical practitioners in Ireland. Given that situation, although the improvement of the guide must remain an essential objective, it may be that the time has come to place patient rights to information about their healthcare within a legal code.

10.4 Recommendations

- 33) The Department of Health should enter into discussions with the Medical Council with the aim of strengthening the guide for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure.

⁶⁶

Lamb R. Open disclosure: the only approach to medical error. *Qual Saf Health Care* 2004; 13:3–5.

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11 Open Disclosure and CervicalCheck

“I personally find it incredibly offensive that someone would know something about my medical state and not pass that information on to me in a timely, clear and honest way.”

11.1 Background

Screening for cervical cancer was well-established in many European countries⁶⁷ in the 1960s. The UK commenced its screening programme in 1988 and the importance of audit and disclosure as an issue in screening services was well known at the time of the inception of the screening programme in Ireland in 2008. The review of cases of cervical cancer by CervicalCheck commenced in 2011 and cases of women diagnosed with cervical cancer dating back to the 2008 were logged. In the first years of the CervicalCheck programme there would have been few women diagnosed with cervical cancer who had a previous screening history with CervicalCheck. The first case to be referred back to the laboratory for review was in October 2012. This was in keeping with the protocol for quality assurance in cervical screening that had been in place in CervicalCheck since 2009.⁶⁸

11.2 Disclosure of Audit Findings

The issue of the disclosure, and even the recording of clinical audit findings has been an issue since the widespread adoption of clinical audits in the late 1980s. Minutes were often deliberately not kept of clinical audit meetings and case review meetings, the belief being that clinicians were more likely to speak openly and honestly if there was no record kept and this would encourage the learning process. However societal and medical attitudes have changed substantially and it is now recognised that patients have a right to know about all aspects of their care, including adverse events and errors. This was helped by a move away from a blame culture and a growing recognition that open discussion and sharing of learning from serious problems was much better for all concerned, above all the patient.

Two key official publications on auditing invasive cervical cancer were published in England in 2006. One provided a detailed guide on how the audit of cervical screening should be carried out, written from a UK perspective.⁶⁹ The other publication dealt specifically with the issue of disclosure of the results of audits in both breast and cervical screening services.⁷⁰ Both publications are grounded in the

⁶⁷ Anttila A, Ronco G, Clifford G, Bray F, Hakama M, Arbyn M, Weiderpass E. Cervical cancer screening programmes and policies in 18 European countries. *British journal of cancer*. 2004 Aug;91(5):935.

⁶⁸ Guidelines for Quality Assurance in Cervical Screening. 1st ed. National Cancer Screening Service. 2009. p101.

⁶⁹ Audit of Invasive Cervical Cancers. NHSCSP Publication No 28. NHS Cancer Screening Programmes. 2006.

⁷⁰ Disclosure of Audit Results in Cancer Screening: Advice on Best Practice. Ed. Julietta Patnick. NHS Cancer Screening Series No 3. NHS Cancer Screening Programmes. 2006.

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fact that an inherent characteristic of screening programmes is that there will always be some cases of cancer missed and audits of past tests will inevitably produce some differences from previous interpretations. The disclosure publication sets out clear advice on the best ways of minimising trauma to both the women involved and the health professionals who must disclose the details.

These important documents predated the adoption of a formal open disclosure policy by the HSE in 2013. As noted in the preceding section, disclosure was touched upon in earlier HSE policies dealing with incident management. The CervicalCheck audit process was however not in the context of an individual 'incident' and, in keeping with the operating protocols for the audit (the first protocol coming into operation on 3 October 2012⁷¹), no communication of the outcome of an individual woman's slide reviews would take place.

It appears from the information available to the Scoping Inquiry that there was initially little knowledge in CervicalCheck of the HSE's policy of open disclosure. The Scoping Inquiry was told that open disclosure filtered down to CervicalCheck in 2014. The first knowledge of the policy may well have been gained because a member of CervicalCheck staff was emailed notice of a training event in 2014 on open disclosure in a local hospital. This only occurred because the person was formerly on the staff of the hospital and was still on the hospital's email distribution list several years later.

Open disclosure was subsequently raised by the staff member at a CervicalCheck meeting and discussions started. The key questions that had to be answered by CervicalCheck in the following months were:

1. Should open disclosure apply in the case of the CervicalCheck audit information, as it was a screening service not a treatment service?
2. If there was to be open disclosure, should it be retrospective?

The eventual decisions were that open disclosure should apply to the audit findings in CervicalCheck and that it should be retrospective.

This was a very significant decision as CervicalCheck had previously only been interested in the information from the reviews of slides being used for future learning and quality improvement purposes within the cytology and laboratory arena. The colposcopists and other clinicians who had been involved in the diagnosis and treatment of the women whose slides were reviewed had previously not been informed of any changes in the designation of slides. The rationale behind that approach was that retrospective knowledge would have had no effect upon the treatment of the women involved.

⁷¹ Process for the review of incident cases of cervical cancer following the introduction of a national cervical screening programme. NCSS CervicalCheck. CS-PUB-PM-10 REV1.

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11.3 Taking the Decision to Disclose

The issue of disclosure was discussed at a CervicalCheck Cancer Review Process Review Meeting on 25th August 2015. This was attended by senior staff from the National Cancer Screening Service (NCSS) as well as CervicalCheck staff. A five-page note of the meeting includes the following elements. A participant in the meeting;

...stated that there is a missing final step(s) in the Cancer Review Process - when delayed diagnoses or other screening incidents are identified, there is no "next step" identified of who should be notified and how this should be done. The consideration is to notify the delayed diagnosis as an incident of potential harm to a woman (and the potential for a legal claim).

The notes on the discussion of this issue of notification refer to it as 'open disclosure' and reach a conclusion that set the course for the limited type of disclosure that followed.

Members discussed open disclosure of cancer reviews within the context of delayed diagnoses. While disclosure directly to the women concerned was discussed, members concluded that disclosure of the outcome of the review to the treating health professional would be the best option.

The issue was on the agenda of the CervicalCheck Executive Management Team on Thursday 28th January 2016. There were two relevant papers on the agenda. The first was an important one-page document titled 'CervicalCheck. Cancer audit process. Status update - 26 January 2016'. It states:

Letters to treating clinicians for cases where the review outcome has been obtained have been drafted for 135 cases (of a total of more than 300). The letters have to be reviewed, finalised and signed by the Clinical Director and Programme Manager. The first letters will issue in February.

The second document was a draft of a revised 'Audit process for incident cases of invasive cervical cancer', dated 25th January 2016, and it states in a section titled 'Communication of audit outcomes':

When the outcome of a case review is complete, correspondence is issued to the treating clinician to inform them of the outcome. This communication of the outcome is intended to support the clinician's interaction and communication with the woman, in addition to contributing to ongoing learning within the screening programme.⁷²

⁷²

Audit process for incident cases of invasive cervical cancer. DRAFT 25 Jan 16. CS/PUB/PM-10 Rev5. CervicalCheck. 2016. p9.

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In a flow chart earlier in the same document the step following 'Report outcome to treating clinician' is baldly stated as 'Case close' and the accompanying text reads, 'The case is closed on the Cancer Audit Log. All documents are filed.' A possible interpretation of these sources available to the Scoping Inquiry is that the women, who have cancer, were not seen as having any autonomy of interest in the findings of a review that provided a different interpretation of their own slides.

11.4 Deciding on the Cases in Which Someone Should Be Informed

Women with cervical cancer, of whom CervicalCheck was aware, had, at the request of CervicalCheck, their slides reviewed by the laboratories that had originally reported on them. Initially the information generated by that review was purely for internal use by the laboratories in the training and quality control functions. When it was decided that open disclosure should be applied to that audit process CervicalCheck went through the results of the reviews by the laboratories. Where the interpretation of one or more slides had altered, and if it was judged that the women's clinical treatment would have been different as a result, they were included in the list of those to whom those results would be disclosed.

11.5 Deciding Who Should Be Told

As noted in the above quote from the draft audit protocol, the person to be notified was the 'treating clinician'. This was, and remains, in keeping with international advice. The possibility of women being informed is mentioned at various places in notes of meetings but the route to that happening, if it happened at all, was the treating clinician. This posed a problem for CervicalCheck. CervicalCheck acknowledges that it generally would not know which cancer treatment centre the woman was, or had been, attending as it does not have an information link with the gynaecological oncology units. However, where the treating clinician's details were provided by the colposcopy clinic, GP or patient, this was recorded on the cancer audit log. It is this doctor who would receive the 'disclosure letter'. Where no treating clinician was recorded, the last known clinician recorded in the colposcopy record was chosen as the recipient (except in a very small number of cases where a GP had been involved in requesting the review).

The result of this approach was that in 90% of the cases identified, the clinician to whom the disclosure letter was sent was one of the colposcopists who participated in the CervicalCheck programme.

"They hid it from us, that's the most painful"

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11.6 Writing to the Clinicians

The first letters to the individual clinicians were sent out in February 2016.

CervicalCheck informed the laboratory company Quest Diagnostics on 3rd February that the dispatch of letters was imminent. While clarifications were initially sought by Quest, these issues were resolved, and dispatch of letters recommenced with the first such letter being sent in June and others following in subsequent months.

The bulk of the letters to the treating clinicians were sent in 2016 and they all contained the same core text. The letter was brief and contained little advice on disclosure to the women involved. The letter in respect of Vicky Phelan is in the public realm and is used in illustration; a copy of this correspondence is attached, with Ms Phelan's permission, in Appendix 3. The first action that the consultant who received the letter was asked to do was to add the correspondence to Ms Phelan's medical record. The next action the doctor was asked to do was consult with the original reporting pathologist(s) to obtain more details in respect of the diagnosis and the potential occurrence of avoidable harm. With regard to open disclosure, towards the end of the letter there is a single sentence paragraph that reads:

If open disclosure is indicated in this case, please follow the local hospital guidelines.

This is unusual, as open disclosure was national policy and there was no expectation that hospitals would develop their own guidelines. There is no other reference to open disclosure in the covering letter, but letters from June 2016, including the one to Vicky Phelan's clinician, were accompanied by a three-page explanatory document. The first such document, for 'consultant doctors', dated June 2016, was only in use in that month, and the second one, for 'health professionals', dated July 2016, was used from July onwards. They both dealt with the background of the audit, the limitations of screening and guidance on whether, and how, to engage in disclosure. The supporting documents also contain advice on how to go about disclosure and the rights of women to information, for example:

Women should be advised on their right to receive copies of all information, including any review reports, and should be given contact details on how to proceed if they wish to do so.⁷³

However, there are also sections of the document that replicate the confused approach in both HSE policy and the HSE/SCA guidelines on disclosure, such as the following which appears in both documents:

⁷³

CervicalCheck. Information for health professionals about the cancer audit outcome. July 2016.

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Clinicians should use their judgement in selected cases where it is clear that discussion of the outcome of the review could do more harm than good.⁷⁴

The interaction that the Scoping Inquiry has had with the women affected has made it abundantly clear that they do not accept that anyone but themselves should have been allowed to make the decision as to whether they were to be given the information.

“The argument that there are some patients who doctors feel ‘don’t want to know’ is NOT an excuse. It was blatantly obvious to all my medical professionals that I was a patient who wanted to know everything about my treatment, yet the letter from CervicalCheck, placed no obligation on anyone to tell me about the audit.”

According to a CervicalCheck staff member, the prolonged period over which the letters to the treating clinicians were dispatched was due to inadequate staff resources. It is not possible for the Scoping Inquiry to make a finding on the opinion of one staff member but the view is noted and another apparent reason for part of delay, namely the clarifications sought by one of the laboratories, is noted above.

11.7 What Happened After the Letters Were Dispatched?

The letters were dispatched to treating clinicians with regards to 207 women. Two of the 209 having been excluded from the process as they had a non-cancer diagnosis. Information has been collated for the Scoping Inquiry in respect of 204 women where the doctor notified was a hospital clinician. In respect of the other three women, the outcome of their reviews was communicated to the GP as it was their GP who had initiated the review by contacting CervicalCheck about their patient.

“Had I received the results of my audit in 2016 my reaction probably would have been that it explained a lot, and that I understand cytology is far from perfect. It makes me quite angry that X took that opportunity away from me. Instead I found out, first from the media, when I suspected I might be involved”

Of the 204 women in respect of whom letters were sent to treating hospital clinicians, disclosure to the women (or relatives) occurred in 43 cases, which represents only one in five. Of those 43 women a record of the disclosure meeting was made in 42 instances. An apology was given in 27 of the 43 cases (63%) and a record made of the apology in 6 of the 27 cases where an apology was said to have been given (22%).

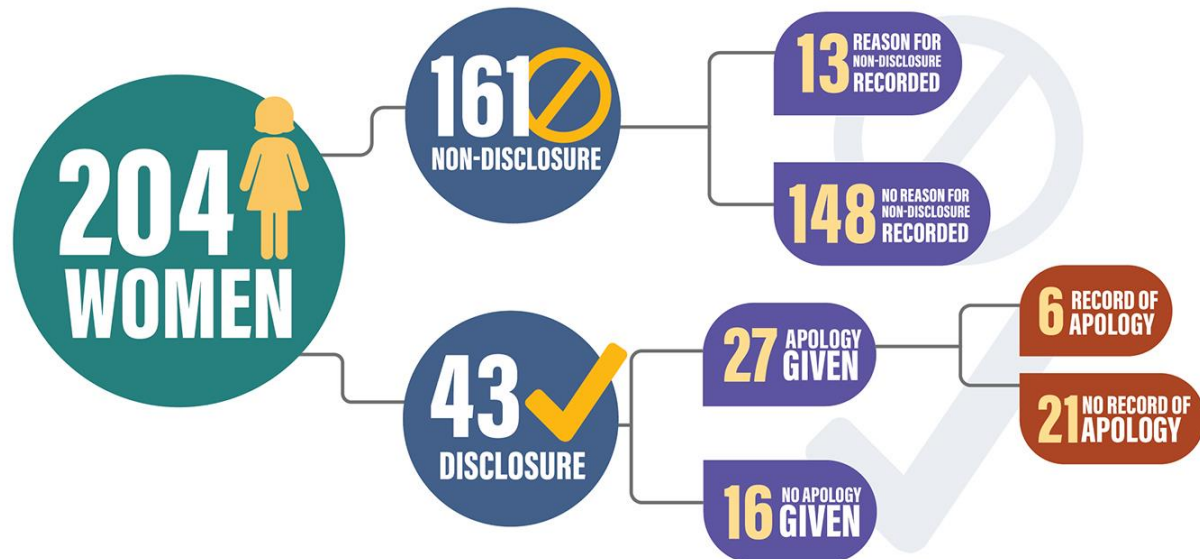
⁷⁴

CervicalCheck. Cancer Clinical Audit Process. Notes for consultant doctors regarding outcomes of the cancer audit process. June 2016.

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OUTCOME OF DISCLOSURE TO WOMEN FEBRUARY 2016 TO JULY 2017

Of the 204 women in respect of whom letters were sent to treating hospital clinicians, disclosure to the women (or relatives) occurred in 43 cases, which represents only one in five. Of those 43 women a record of the disclosure meeting was made in 42 instances. An apology was given in 27 of the 43 cases (63%) and a record made of the apology in 6 of the 27 cases where an apology was said to have been given (22%).



These data are not in keeping with what is meant to happen, according to the HSE/SCA guidelines on implementing open disclosure issued in 2003. According to the guidelines document, non-disclosure, such as happened in four out of five cases, is supposed to be exceptional.

NOTE: Only in exceptional circumstances, based on the clinical interests of a service user, is it likely that a service user will not benefit from open disclosure. The reason(s) for non-disclosure should be documented by the clinician in the service user's clinical record and senior management should be informed via internal governance processes. Decisions in relation to disclosure/non-disclosure should include input from the multidisciplinary team.⁷⁵

The HSE/SCA guidelines also state that an apology is necessary:

Following an adverse event where a service user has been harmed as a result of their health care an expression of regret or an apology is necessary and often very valuable.⁷⁶

⁷⁵ HSE - SCA. Open Disclosure: Communicating with service users and their families following adverse events in healthcare. 2013. p46.

⁷⁶ Ibid p49.

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And that any such apology should be recorded:

An apology/expression of regret can sometimes be inferred by the service user as an admission of liability therefore the exact words used and the context in which the apology is provided should be documented in the minutes of the disclosure meeting and in the clinical record.⁷⁷

There was also a specific statement in the HSE/SCA guidelines that a distinct and specific ‘open disclosure file’ should be created for each patient.

An “open disclosure file”, separate to the healthcare record, should be opened to communicate other information not necessarily required for documentation in the healthcare record, e.g. minutes of the meetings, details of reviews undertaken, statements from staff etc.⁷⁸

It was hoped that examination of these files would yield valuable information for the Scoping Inquiry about the open disclosure process at hospital level. But in no case was such a file created.

It was also hoped that, in cases where a decision was made not to tell the woman, the individual patient’s notes would contain the reasons why non-disclosure had happened. This would have been in keeping with the HSE/SCA guidelines quoted above. However, in the case of the 161 women who were not told, only 13 (8%) had the reason why they were not told recorded in their records.

According to information provided to the Scoping Inquiry by CervicalCheck, for the three women whose disclosure letter was sent to their GP, information is only available for two of them. Disclosure happened in one case, but there was no apology or record kept. No disclosure happened in the other case and no record was kept. In the third case, the practice has closed and information is not available as to what happened.

The professional code of conduct that applies to doctors in Ireland, produced by the Medical Council, includes a section on record-keeping.

33.2 You must keep accurate and up-to-date patient records either on paper or in electronic form. Records must be legible and clear and include the author, date and, where appropriate, the time of the entry, using the 24-hour clock.⁷⁹

It is notable that the word ‘must’ is used in the above paragraph – leaving no room for doubt as to what is expected of doctors in terms of record keeping.

⁷⁷ Ibid p50.

⁷⁸ Ibid p54.

⁷⁹ Comhairle na nDoctúirí Leighis. *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*. 8th Edition, 2016.

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One of the women was told the result of the review of her case by telephone in October 2017. The nurse who called, explained that the audit was a 'routine investigation that helps craft future learning', and the patient was invited to the hospital to discuss the results. When she attended, she was met by the registrar, not the consultant. The registrar read out the new result for the slide, 'high grade changes', and she was recommended to go back to the city where she was now being treated and discuss it with her gynaecologist there.

11.8 How Non-Disclosure Occurred in the Majority of Cases

It is clear that CervicalCheck was, in principle, in favour of disclosure of the results of the audit to the women involved. However, the decision to hand responsibility for disclosure to the treating clinicians left the effective decision with those clinicians. The medical literature on disclosure makes it clear that not all women who develop cervical cancer want to know about the results of a review that included their slides and histology.

....our audit shows that less than one-half of patients with invasive cervical cancer appear to want to know how they developed their disease despite participating in a screening programme.⁸⁰

On the other hand, there is evidence in the medical literature that patients in general do want to be told when something goes wrong with their care.

Patients were unanimous in their desire to be told about any error that caused them harm. Patients believed such disclosure would enhance their trust in their physicians' honesty and would reassure them that they were receiving complete information about their overall care.⁸¹

In the case of disclosure of results from the CervicalCheck review, the material available to the Scoping Inquiry documenting the decision about how the women should be informed did not include any suggestion that the woman herself might have a say in the matter. Rather, in many cases, it became a matter of dispute as to:

- a) whether the woman should be informed at all, and
- b) who should be responsible for delivering the news to the woman.

A lengthy correspondence, that is in the public realm, between the treating clinician in Vicky Phelan's case and CervicalCheck about the process of disclosure highlighted these dispute.

⁸⁰ Prabakar I, Moss EL, Douce G, Parkes J, Redman CW. Review of invasive cervical cancers and uptake of disclosure of results: an audit of procedures and response. *Cytopathology*. 2012 Jun;23(3):167-71.

⁸¹ Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. *JAMA*. 2003; 289(8):1001-1007.

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As outlined in Section 9 of the report, HSE policy and the HSE/SCA guidelines are unhelpfully equivocal in that they state both that patients should be told but also that a clinician can decide not to tell them. The CervicalCheck approach was to leave the decision on disclosure to the treating clinician. In the case of this retrospective audit of women who had developed cervical cancer, many of them had completed treatment, sometimes several years previously, and the situation was entirely different to a case where an error was made or uncovered during the course of active treatment, for example a medication error in respect of a hospital inpatient. It is clear from the correspondence that the lead colposcopists, who were in most cases identified as the 'treating clinician', were, in the main, very unhappy about the approach chosen by CervicalCheck. The colposcopists felt that they had not been involved in the design or carrying out of the audit, and that it should have been CervicalCheck centrally which took the disclosure decision and told the women.

This dispute about disclosure between the colposcopists and CervicalCheck centrally went on over a substantial period of time and was never resolved satisfactorily. The correspondence which commenced in relation to Vicky Phelan's case and those of others, developed into a broader concern.

From the material provided to the Scoping Inquiry, and from interviews and meetings with those affected, it appears that there was no system put in place to monitor whether or not disclosure to the women and relatives actually happened. There was some communication from clinicians in a very few cases about how the disclosure had gone, but that information was volunteered rather than being sought actively.

It also needs to be noted that the approach to the cases of women who had died before the decision had been made in respect of disclosure was that nothing should be done other than the disclosure letter and slide results being placed in her medical records. From the material provided to the Scoping Inquiry, it appears that this approach seems to have been adopted without discussion or debate.

Despite the fact that the colposcopists were key medical consultants in the CervicalCheck screening programme, and that part of their time was funded by the HSE on that basis, there were no regular meetings held to discuss the screening programme with them. There was however an annual educational forum for colposcopists where relevant issues were the subject of presentations and discussions in that arena.

The first, and only, meeting of the lead colposcopists held with CervicalCheck took place for one hour on 1 September 2017 and the 'cancer audit' was one of the items on the agenda.⁸²

This short meeting involved six of the lead colposcopists in person; three joined the meeting electronically; and apologies were recorded for six others. The notes of the

⁸²

https://data.oireachtas.ie/ie/oireachtas/committee/dail/32/committee_of_public_accounts/submissions/2018/2018-05-17_correspondence-health-service-executive-hse-ii_en.pdf

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meeting record that a 'robust discussion' took place in respect of the cancer audit process. Six key points from this discussion are recorded. Two points are of particular note in relation to disclosure. They read:

A perception that putting the onus on the clinicians to initiate the conversation was not correct and caused a deal of concern and negative feelings towards the programme from clinicians.

In the absence of clarity regarding the assessment of harm that clinicians were being put at a disadvantage when deciding who should and should not be offered a close out meeting.

These points, and others, reflect the clear dissatisfaction of the colposcopists with the approach to disclosure. It is recorded in the notes that, in response, there was an expression of regret for any negative impact and an explanation of how the process had evolved from being primarily for quality improvement and educational purposes.

11.9 Disclosure Following the Vicky Phelan Court Case

After Vicky Phelan's case came to court, dramatic changes occurred and there was a strong media and political focus on making sure women and the families of the deceased were informed as quickly as possible. Yet again, the process adopted was relatively unstructured. This time it was focused on achieving disclosure in an extraordinary glare of publicity and an extremely short timeframe. The people turned to were mostly the same lead colposcopists who had been previously sent the disclosure letters. As noted above, in the substantial majority of cases they had already made a decision not to disclose for reasons that were not recorded. This time, however, disclosure was not optional, and instructions were issued by the HSE's Serious Incident Management Team. The Chief Executive Officers of the hospitals involved were asked that, at a minimum, the woman or her next of kin were to be informed:

1. That their cytology was reviewed as part of an audit conducted by CervicalCheck.
2. The date on which the audit was complete.
3. How the review details may relate to their subsequent cancer diagnosis.

The approach adopted varied, but the views of the women and families involved in this round of disclosure were heard very clearly by the Scoping Inquiry at the meetings held in Dublin, Cork and Galway; in meetings and telephone discussions with individual women and relatives; and by email and letter. There was a very strong feeling that disclosure was handled badly in most cases, and sometimes very badly indeed.

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“When this story broke, the drip feeding of the information through the media and lack of robust, timely and accurate information gave a real sense of both paternalistic secrecy and incompetence by CervicalCheck.”

The women or relatives were generally contacted by telephone and told that they were part of the group of 209 women who had been the subjects of the audit. They were, in the majority, usually invited to attend an appointment to be informed of the results. Many women recounted that these appointments were extremely

stressful and sometimes highly traumatic. The Scoping Inquiry has been told that at least three of these meetings were held in the same room where the women had originally been informed of their cancer diagnosis. In one of those three cases it also happened, by chance, to be the room in which the woman’s mother had died.

Many of the women and relatives to whom the Scoping Inquiry has spoken were extremely upset at how the disclosure meetings were conducted and, in particular, the answers they received to their questions.

“When I tried to question my oncologist further on what this meant and if I had cancer three and a half years prior to diagnosis, he shut down, refused to answer the simplest of questions, and ushered me out the door with no support and many questions.”

The women and relatives were particularly concerned to know why, if the information had been available to the consultants in 2016 and 2017, they hadn’t been told then. They often recounted that the attitude and responses of the consultants to the question were negative and defensive.

“He said, ‘I withheld information from you.’”

“He said he didn’t know the protocol.”

“He said it had got lost in the file.”

“He said it was caveated not to disclose.”

“He basically lied to me.”

“He couldn’t look me in the eye.”

“He had seen I had had a hysterectomy and decided I didn’t need to know”

One woman recounted the interaction with her consultant as follows:

Woman: “Why didn’t you tell me? Why didn’t you tell my clinicians?”

Consultant: “What difference does it make?”

Woman: “How will I be informed from now on?”

Consultant: “Watch the news.”

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One of the most disturbing accounts was relayed by the close relatives of one of the women who is deceased. As part of the disclosure meeting, the consultant mentioned several times that the late woman was a smoker (it is known that smoking impedes the body's ability to clear itself of the HPV virus) and they were also told that 'nuns don't get cervical cancer'.

It is however true that there were disclosure discussions that were well handled and about which no complaints have been voiced. But the anger of many women and families about how they have been treated in respect of disclosure is intense and raw. They simply cannot accept that they were given no opportunity to decide for themselves whether or not they wanted to know this information about their own slides.

11.10 Analysis

It must be recognised that there was a genuine desire on behalf of CervicalCheck to give women who had developed cancer the opportunity to learn about the audit that had taken place, that there had been a different interpretation placed on at least one of their earlier cervical slides, and that this might have altered their treatment if it had been the original finding. It was extremely unfortunate that this policy was not pursued in a structured and planned fashion, using an approach that consulted interested parties, including patient advocates, and took into account the readily available evidence and guidance on how this type of exercise should be conducted.

Despite the fact that funding for the colposcopists' time in providing care to patients referred after screening is attributable to CervicalCheck, they didn't regard themselves as part of CervicalCheck. They had not been involved in designing the audit, or in the discussions leading up to the decision to disclose the results of the review of slides by the laboratory. There was only one official meeting (as distinct from educational events) between the senior staff of CervicalCheck and the lead colposcopists in the entire history of the screening programme, further contributing to the general failure by many of those involved, whether employed by CervicalCheck or funded by them, to engage fully with their patients.

This disconnect was added to by a letter from CervicalCheck that placed responsibility on the receiving clinician to identify and contact the cytopathologist of the laboratory concerned to discuss cases. The letter also left the judgement to the consultant as to whether or not disclosure was appropriate. The June 2016 document from CervicalCheck, that accompanied some of the disclosure letters, 'Notes for consultant doctors regarding outcomes of the cancer audit process', was, to say the least, equivocal about the application of open disclosure.

While CervicalCheck supports the principles of open disclosure, it is recognised that there are limitations to its universal implementation, particularly for screening services where there is an inherent recognised error rate. The assessment of avoidable harm that doctors are asked to

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make, which should be done in consultation with the relevant consultant doctors, should take this into consideration.

When disclosure in the substantial majority of the cases eventually happened, it was hurried and took place against a fevered media and political backdrop. The way in which women and families were treated was responsible for substantial hurt and anger. Most seriously of all, it resulted in an extremely serious loss of confidence by many women in the clinician who was responsible for their treatment. Women were left wondering if a doctor who could not be trusted to tell them the honest truth about their screening, could be trusted to provide them with the best care.

“To think I’ve gone to him over the years and he has said nothing.”

There was an alternative option; it didn’t have to be like this. The guidance published by the NHS in England in September 2016 contains valuable advice on how to disclose the findings of an audit.⁸³ There is evidence that disclosure can be done well from another cancer screening issue in Ireland involving the BowelScreen programme. Professor Steele’s external review of the incidents in Wexford concluded that

...disclosure was handled in an appropriate and timely manner.⁸⁴

From the material provided to the Scoping Inquiry, it appears that the willingness and ability of the staff of CervicalCheck to develop, implement and disclose the audit was compromised by the inadequate overall level of staffing, the skill mix of staff and the management arrangements that were in place. These issues are addressed elsewhere in this report.

A situation where an organisation can be allowed to impede the speaking of truth to patients in relation to their healthcare is totally unacceptable. Nor should it be acceptable for an organisation to give permission to health professionals, of whatever seniority, to withhold the truth from patients. In recent years two major public inquiries, one in England in 2013 (the Francis Report) and one in Northern Ireland early in 2018, have recommended the adoption of a statutory duty of candour on organisations and individuals. Mr Justice O’Hara, in his recent report on the deaths of five children in Northern Ireland hospitals was explicit about what needed to be done.

A statutory duty of candour should now be enacted in Northern Ireland so that:

- (i) Every healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public.⁸⁵*

⁸³ Public Health England. Guidance on applying Duty of Candour and disclosing audit results. V1.0. September 2016.

⁸⁴ Steele RJC. External Review of NIMLT case 50796. HSE. January 2018.

⁸⁵ Mr Justice O’Hara. The Inquiry into Hyponatraemia-related Deaths. Jan 2018. <http://www.ihrdni.org/Full-Report.pdf>

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The same approach was recommended by the Oireachtas Joint Committee on Health and Children in a report in June 2015.⁸⁶

A duty of candour should be regarded as absolute for Irish health professionals.

The Committee's recommendation made a very specific call for;

...measures to introduce stand-alone legislation placing an onus on health service staff to inform patients when mistakes or errors occur.

The Minister for Health at the time put it very clearly when speaking at the Committee hearing on 5th February 2015.⁸⁷

Failing to disclose openly and not adhering to a duty of candour, for me, is the equivalent of a hit and run...

These sentiments supporting a duty of candour being placed on healthcare professionals have, unfortunately, not yet resulted in enactment of the appropriate legislative framework.

11.11 Recommendations

- 34) A statutory duty of candour must be placed both on individual healthcare professionals and on the organisations for which they work.
- 35) This duty of candour should extend to the individual professional-patient relationship.

⁸⁶ Houses of the Oireachtas. Joint Committee on Health and Children. Report on the Cost of Medical Indemnity Insurance. 31HHCN20. June 2015. p16.

⁸⁷ Dáil Éireann. A Select Sub-Committee on Health. 5th February 2015. p23.

12 Cancer Registration

12.1 Background

The National Cancer Registry, Ireland (NCRI), in common with other national cancer registries, strives to collect data on all people diagnosed with cancer who live or are diagnosed in the jurisdiction. For some types of cancer, especially those such as breast, cervical or colorectal cancers for which there is a screening programme, they may also collect data on pre-cancerous lesions as part of the cancer registry's contribution to quality assuring the effectiveness of the screening programmes.

Data is collected from a variety of sources, largely from hospital services but also from other sources such as death certification, to populate a record for each patient diagnosed with cancer. In addition to patients' vital information such as date of birth and address, the cancer registry will collect information for each patient which may include:

- date and mode of detection of cancer;
- date of actual diagnosis;
- details from cytology or histopathology including stage and grade if available;
- types of treatment;
- recurrence of cancer or new cancers;
- date and cause of death.

Cancer registries play an important role in cancer control through undertaking epidemiological and audit analysis of the data that they hold. For example, cancer registries can provide information on numbers of new cases and deaths, survival, type and quality of treatments and trends in all of these. They also give an insight into who is most at risk of developing different types of cancer by gender, age, socioeconomic status and perhaps place of residence, and whether health services are equally accessed by all those who could benefit. These analyses can be used to formulate and assess the effectiveness of prevention, screening and cancer treatment programmes at each stage of the patient journey through to end of life care.

12.2 The Role of Cancer Registries in Evaluating Cancer Screening

Cancer registries in the UK and worldwide have, for over 30 years, played a major role in the quality assurance (QA) and evaluation of effectiveness of cancer screening programmes.

Acting alone, a cancer registry can monitor time trends in the numbers of cases of invasive cancer and precancerous conditions and the stage at which these are diagnosed, survival, and mortality. The influence of the introduction of a screening

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programme on these indicators can thus be crudely evaluated by monitoring in the screening age group:

- Initial increases in detection rates of cancers and precancerous lesions followed by reductions if screening is successful;
- A stage shift towards the detection of earlier stage cancer;
- Reduction in mortality and improved survival.

Cancer registry data can also be used to predict the effect of introducing new interventions, such as the impact on cervical cancer of HPV vaccination or screening.

However, without information on the individual patient's screening history, dates of screens and results it is not possible, for example, to determine whether patients diagnosed with advanced stage cancer were never screened, screened but with longer than the recommended interval, screened within the screening interval and that there might have been a problem with the results of the screening test, or whether they have a very aggressive form of cancer.

This information can be used to undertake a number of analyses important to understanding the quality and effectiveness of the screening programme. This would include, for example, the proportion of women in the screening age group who had their cancer detected by screening. Health policy makers may want to know if there are particular groups who do not take up the offer of screening, so that they can engage in health promotion or other facilitation to encourage people to attend. They would want to know if the interval between screens is extending longer than that recommended, for example because of lack of trained screening personnel and if so, has this resulted in more patients being diagnosed with advanced disease? Finally, one of the most important ways of assessing how effectively a screening test is performing is to check the screening test results of all cases who have had a cancer diagnosed.

Comprehensive quality assurance can usually only be achieved thoroughly through data exchange between a national screening programme and the relevant national cancer registry. The national cancer registry has data on all cancers diagnosed and the screening programme has data on all screening tests undertaken and their results. In an ideal system screening tests, dates and results, if the patient has been screened, are matched with patient's cancer diagnoses. It is only in this way that the screening status of each person diagnosed with cancer is known.

12.3 The National Cancer Registry Ireland

NCRI was established by the Minister for Health in 1991 and is wholly funded by the Department of Health. It is based in Cork and its basic function is to record information on all cancer cases occurring in Ireland, which it has been doing since 1994. The NCRI Director reports to the National Cancer Registry Board, which has six members, and the Director is responsible, amongst other things, for the

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production of an annual report on the activities of the Registry. The most recent annual report was published in November 2017.⁸⁸

12.4 Registration of Cancers

Since its inception NCRI has been permitted by law to collect actively information on all cancer cases and has sought to register information on all cancers diagnosed in Ireland, receiving information from hospitals, death certificates and other sources. Data transfer from hospitals to NCRI does not require the patient's permission for this transfer to occur. Cancer Data Registrars are located in hospitals to facilitate access to this data. NCRI has experienced problems in obtaining information in some hospitals and delays in recruiting staff to vacant positions.

It is correct to say that NCRI is not directly involved in the clinical care, audit, or quality assurance of the patients' care. However, whilst it is clear that cancer registries do not take part in patients' clinical care, many do undertake and contribute to audits of the quality of cancer control programmes, including screening, cancer treatment, and even end-of-life care for cancer patients.

12.5 Cervical Cancer Registration

In addition to its routine methods for collecting data on cancers from hospitals, NCRI receives data on cervical cancers and pre-cancerous cervical intra-epithelial neoplasia (CIN)⁸⁹ lesions from CervicalCheck. NCRI uses this data to supplement its cancer registration database. It adds cancers for which it did not already have a record because of difficulty or delays in getting data from some hospitals, supplements the data it has on cancer cases and adds CIN data which it would not otherwise obtain.

It is interesting that CervicalCheck established its own collection and collation system for cervical cancers and CIN from hospitals, in particular from colposcopy services. It appears that, for some services, CervicalCheck may have had better relations in terms of receiving data than NCRI as evidenced by notes from a meeting in March 2015 which documented that NCRI received an extract of all relevant cervical cancers from CervicalCheck for 2011 to 2013 which was used to 'close' 918 existing registrations for four hospitals: CWIUH, the National Maternity Hospital (NMH), Galway University Hospital, and Our Lady of Lourdes, Drogheda. Furthermore, it was used to create and 'close' 1012 cases for NMH for 2011 to 2013.

Of note also, from data shown in documents from NCRI that have been reviewed by the Scoping Inquiry, it appears that CervicalCheck collects data not only on cervical

⁸⁸ Cancer in Ireland 1994-2015 with estimates for 2015-2017: Annual Report of the National Cancer Registry. NCRI. Nov 2017. <https://www.ncri.ie/publications/statistical-reports/cancer-ireland-1994-2015-estimates-2015-2017-annual-report-national>

⁸⁹ Cervical intra-epithelial neoplasia is the abnormal growth of cells on the surface of the cervix that can potentially lead to the development of cervical cancer.

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cancers and CIN diagnosed through the screening programme but also data on some cancers diagnosed in symptomatic patients. Indeed, it appears that NCRI saw CervicalCheck as a useful source to supplement their cancer registration data, especially from locations from which they were having difficulty obtaining information. In the notes of a telephone conversation in March 2016, CervicalCheck stated that they believed they had data on 79% of cervical cancers diagnosed in Ireland. In a 2016 analysis presented at a meeting with NCRI it was clear that 39% of the cervical cancer patients, for whom CervicalCheck had data, were not directly detected through the screening process.

It appears that attempts were made to reconcile the total numbers of cervical cancers diagnosed in Ireland by comparison between the numbers collected by CervicalCheck and NCRI. As described above, CervicalCheck sends data on cancers it has on its data base to NCRI. This allows for the number of cancers recorded by CervicalCheck and not initially by NCRI to be established. NCRI then shared the number, but not the actual details cases of cancers it registered of which CervicalCheck were unaware.

There is evidence that staff from the NSS, NCRI, and CervicalCheck were aware for several years of these parallel data collection systems for cervical cancer. They were all aware that neither was complete and that the full sharing and checking that would have been required to create a complete data set of patients with cervical cancer and their screening records, did not take place. Despite this awareness, no decisive action was taken to resolve this unsatisfactory situation. It is clear that the organisations worked around the inadequacies in data without actually taking action to resolve them.

12.6 Data Sharing between CervicalCheck and NCRI

It is clear that data sharing issues existed between NCRI and CervicalCheck. NCRI receives data on cervical cancers and CIN cases from CervicalCheck but had not transferred any details of cases of cervical cancer to CervicalCheck until instructed to do so in May 2018 by the Minister for Health.

NCRI had previously only given numbers of cases and aggregated statistics to CervicalCheck. This inevitably hindered the scope of the quality assurance of the cervical screening programme as neither CervicalCheck nor NCRI had a full dataset of all cervical cancers diagnosed and their screening status.

This problem is illustrated by an exchange which took place in October 2014 between NCRI and the NSS on numbers of cervical cancer cases. It was noted that CervicalCheck had knowledge of approximately 900 cervical cancers and NCRI approximately 1,200. There were attempts to rationalise this difference by limiting the comparison to only 25-59 year olds, although it was acknowledged that there might still be some difference. It was also suggested that the difference in totals could be due to differences in the time periods covered. Without full two-way exchange of data and checking of cases these important issues could only be matters of speculation.

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The notes of a meeting between staff of NCRI and NSS held on 3rd October 2014 indicated that a significant discussion of interval cancers in breast screening had taken place. There is also a short section to the effect that to assist in cervical interval cancer ascertainment CervicalCheck needs to send a file of demographics of screened women for linkage. This is followed by an email on 15th October 2014 giving details of fields needed for linkage stating that, 'this is the first attempt at linking the two data sets'. Elementary data on screening status is included in this data transfer. NCRI adds a screening flag to the cervical cancers but this does not seem to have a classification linked to the screening programme, i.e. true interval cancer. In an email of 21st September 2017, it was stated that all cancers notified first to NCRI from CervicalCheck are labelled as 'screening'. There also seems to be an issue about the classification of whether cancers are detected through screening or opportunistic testing.⁹⁰ This limits the potential usefulness of the analysis NCRI can conduct on the effectiveness of the CervicalCheck Programme.

It is not clear why no progress has been made in two-way sharing of individual patient data between NCRI and CervicalCheck. Patient consent and confidentiality appears to have been perceived as a barrier to the transfer of data from NCRI to CervicalCheck although not from NCRI to the Breast Screening Programme. For cervical screening, the consent statement was interpreted as meaning that data on cancers diagnosed through the CervicalCheck and on precancerous lesions could be sent to NCRI to complete their cancer records. The wording of the information sheet accompanying the consent form completed by women undergoing cervical screening includes the statement:

*We will share your screening history with laboratories, colposcopy clinics and, where applicable, the National Cancer Registry so they have an accurate record of your screening history.*⁹¹

On 24th September 2009 at the first meeting of the National Cancer Registry Board there was a discussion of matching data from BreastCheck to NCRI, 'to measure the number of cancers missed (interval cancers) by the screening process'. It was also stated that a similar service will be required with the national roll out of cervical screening. In February 2010, a letter from the CEO of the NCSS to the Director of NCRI outlined that the then recently published '*Guidelines for Quality Assurance in Cervical Screening*' included a CervicalCheck programme standard (Section 2.1.5) that required that a process must exist to facilitate cancer audit.⁹² This programme standard includes the following specific explanatory note (referenced to the internationally recognised handbook on cervical screening⁹³) stating that:

⁹⁰ Opportunistic testing is when a patient requests a check or a test or is offered one by their healthcare provider rather than availing of one through a formal screening programme.

⁹¹ Information Sheet for Women. CervicalCheck. <https://www.cervicalcheck.ie/fileupload/Health-professionals/HPForms/CS-F-LAB-2%20Cervical%20Screening%20Form.pdf>

⁹² Guidelines for Quality Assurance in Cervical Screening. CervicalCheck, 1st Edition, 2009. <http://www.lenus.ie/hse/handle/10147/107594>

⁹³ IARC Handbooks of Cancer Prevention. Vol 10. Cervix Cancer Screening. <https://www.iarc.fr/en/publications/pdfs-online/prev/handbook10/HANDBOOK10.pdf>

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This involves linking cervical screening data with National Cancer Registry of Ireland (NCRI) data. A comprehensive evaluation with a systematic audit process of the entire screening programme can be performed.

The CEO of the NCSS asked the Head of Cervical Screening to chair a group to develop this audit process for cervical cancer and asked for a nominee of NCRI to sit on the group. This letter also stated, 'It is incumbent on us to develop a process within the Irish Healthcare system that will flow within hospital clinical risk management structures and lead to common standard operating procedures through the country'. The terms of reference of the group were to:

- Review cancer audit processes in place in other countries
- Examine options in developing a cervical cancer audit process
- Formulate a preferred option for cervical cancer audit in Ireland

The first date for a meeting of the Cervical Cancer Audit Group was set for the 26th March 2010 and various participants invited. Unfortunately, no papers have been located for this meeting. However, notes have been reviewed from a meeting on 17th May 2010 between NCRI and CervicalCheck on the subject of 'data for audit of invasive cancers'. The stated aims of that meeting were in four parts:

1. Identify all invasive cancer.
2. Match these to CervicalCheck records.
3. Determine the screening history of the women.
4. Allow a trace-back of the screening process (if any) prior to diagnosis.

A further nine-part process was suggested that included a case-matching process involving both organisations. It was agreed to undertake a test of the matching process, which occurred in June 2010. In May 2010, there was a reference in the NCRI Senior Management Team meeting notes that CervicalCheck 'would like to trace every woman diagnosed with invasive cervical cancer. This will involve linking cervical screening data with registrations'.

There is evidence of the first data transfer in June 2010 from CervicalCheck to NCRI and an attempt at linkage. This was followed in September 2011 by discussions of NCRI having access through the NCSS to an online data system 'Little CSR' containing data on all smears, colposcopy and pathology data. On 29th May 2014 there was an email confirming that CervicalCheck was happy to provide data to NCRI in the light of the 'longstanding agreement (signed 2011) between NCSS and NCRI'. A copy of the two-page agreement from September 2011 has been obtained, but only signed by the head of NCSS with the space for the signature of the head of NCRI left blank. The stated purpose of the agreement was to facilitate access to data and information and exchange of data and information related to identified cases of invasive and in situ cervical cancer. The defined scope of the agreement states that:

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NCSS will provide access to the NCRI to information stored on the Cervical Screening Register (CSR) in order to allow NCRI to determine if a notified case of cervical cancer concerns a woman who has consented to participation in the CervicalCheck Programme, and to obtain the screening history and other information necessary for cancer registration, if any, for that woman contained on the CSR.

NCRI will inform NCSS of notified cases of cervical cancer for women who have previously consented to the CervicalCheck programme, in order to contribute potential additional cases to the NCSS Cervical Cancer Review process.

There was also a note on consent in the agreement.

A woman provides by signature her informed consent to participate in CervicalCheck, the national cervical screening programme. The information provided to the woman includes the information that her data may be shared with the National Cancer Registry of Ireland.

This agreement was due to commence on the 26th September 2011 and stated that it would:

... remain in force for a period of twelve months after which it is subject to review by both parties (or such longer date as may be agreed between the parties) unless and until terminated earlier in writing by either party.

The significance of this contract was that only data on women known to have given consent for cervical screening would be transferred from NCRI to CervicalCheck. This means that only NCRI would be able to determine fully how many women had cervical cancers diagnosed outside the screening programme. It is not clear whether women with interval cancers would fall into this category if they presented symptomatically or whether by virtue of ever having been screened it would be deemed that their data could be shared from NCRI to CervicalCheck. As NCRI would be the only organisation with a complete data set for women diagnosed with cervical cancer, it would be incumbent therefore on NCRI to perform a public health function and conduct an analysis to understand the characteristics of women diagnosed with cervical cancer, including those who have not been screened, to inform health promotion and other public health strategies. In this light it seems a distinct disadvantage not to have full system agreement on how to classify screening status on the NCRI database, as appears to be the case.

The agreement was only for twelve months and no evidence has been seen of a review of this contract, or either extension or termination. It appears from the email correspondence referred to above that CervicalCheck believed the agreement still to be in place in 2014 although there appears to be no firm written basis based on any documentation that the Inquiry has seen for that belief. On the 4th March 2016, there was a request from CervicalCheck to NCRI for information with respect to an audit. It

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appears that at no time from 2010 was cervical cancer data transferred from the NCRI to CervicalCheck, even in respect of women who had consented to CervicalCheck, until a request was made on 4th May 2018 by the Minister for Health on the grounds of significant public interests and based on the functions detailed in the order which established NCRI.

The reason given for the non-transfer of cervical cancer data to CervicalCheck was that there was no data sharing agreement in place. Over a period of eight years there is no evidence of concerns about barriers to the transfer of data from NCRI to CervicalCheck being raised officially with the NSS or the Department of Health.

At the beginning of 2018, NCRI initiated a full review of policy and procedures on the handling of patient data in preparation for the new EU General Data Protection Regulation (GDPR) May deadline. In February 2018, there was evidence of NCRI checking with a consultant they had employed to advise on GDPR implementation, whether they could share staging information on individual patients with the Bowel Screening Programme and were told by the consultant that they could not unless they had the patient's consent. At this time, NCRI acknowledged that the issue probably affects the transfer of data for CervicalCheck, as the context of the consent indicates that it allows for the screening service to 'share data with us (NCRI) and not vice versa'. It was believed that the wording of the consent in Breast Check was clearer in that 'consent is for 'data exchange' so covers transfer in both directions'. However, concern was raised in NCRI that this has some potential problems in that wording of the consent contains the words, 'if an abnormality is detected', suggesting that information could only be transferred if BreastCheck had a record of an abnormal mammogram.

In May 2018, the Minister for Health in addition to requesting an immediate onetime request for transfer of data from NCRI to CervicalCheck, also wrote:

To allow for ongoing identification of interval cancers for CervicalCheck and other screening programs I urgently request a 2-way data transfer agreement be put in place between the HSE and NCRI.

The letter points out that Article 4 (c) of the order which established NCRI states that one of its functions is to promote and facilitate the use of data thus collected in approved research projects and in the planning and management of services.⁹⁴

This suggests that perhaps in fact NCRI could have always transferred data to CervicalCheck under Article 4 (c) for the purpose of planning and management of the Cervical Screening Service. The Ministerial letter also makes clear that the introduction of GDPR will now require a two-way data transfer agreement with the HSE so that both NCRI and HSE can transparently 'determine their respective responsibilities for compliance' with the Regulation.

⁹⁴

S.I. No. 19/1991 - The National Cancer Registry Board (Establishment) Order, 1991. <http://www.irishstatutebook.ie/eli/1991/si/19/made/en/print>

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12.7 Other Data Sharing Issues Relevant to Quality Assurance

Assessing the quality of treatment services given to patients detected through screening programmes is an important component of quality assurance (QA) of screening programmes. NCRI can return data on cancers to a specific clinician about the patients they have treated but under NCRI's interpretation of current legislation, in Ireland, NCRI cannot, for example, send back to a hospital all the details of the cancer patients treated at the hospital for whom NCRI has a record. This may hinder quality control of the registration process and other quality control activities, such as clinical audit, for cancer services in the hospital or between hospitals where care is shared. On closer examination, it may be determined that Article 4 (c) of the order does in fact permit, for example, system based clinical audit activity using NCRI data.

12.8 Governance of the NCRI Contribution to Quality Assurance of CervicalCheck

The governance arrangement for the role of NCRI in supporting the QA of cancer screening programmes is not clear. It is difficult from the documentation supplied to understand the governance structures for cervical screening QA and how in practice governance would be exerted in respect of NCRI. The Registry has had a separate relationship with each of the screening programmes in addition to the overlapping relationship with the NSS under which the screening programmes sit. The reporting arrangements and leadership are unclear, as is the expectation of the cancer registry. There is no evidence of any written contract or Memorandum of Understanding in respect of cancer screening except for the aforementioned incompletely signed 2011 contract of 12 months' duration detailing data exchange with CervicalCheck.

The documents made available to the Scoping Inquiry and discussion with both the current Director of NCRI and the previous Director suggest that the Registry played a supportive rather than a proactive role in contributing to cancer screening quality assurance, i.e. responding to requests. In response to those requests there is evidence of discussion and sharing of analyses of cancer incidence, stage at diagnosis and mortality data by screening and non-screening age group.

12.9 Missed Opportunities to Ring Alarm Bells

The documentation made available to the Scoping Inquiry indicate that discussions between NCRI, CervicalCheck, and the NSS seem to have focused on analysis to detect any reduction in incidence of cancer and a stage shift towards cancers being detected at an earlier stage. The notes from a teleconference between CervicalCheck and NCRI on 13th January 2017 show, for what seems to be the first time, a comprehensive plan to use data to quality assure the CervicalCheck programme as a national screening programme. The only major omission seems to be the use of the word 'interval cancer' and discussion of definition and importance. Based solely on consideration of the above mentioned notes, there seems to have

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been a blind spot regarding the ascertainment and analysis of interval cancers in the CervicalCheck programme in all the records of meetings reviewed since 2010.

There is no evidence in the notes of clear leadership and expertise in the clinical interpretation and relevance of data in the screening context. There is little or no evidence in the notes of meetings of the attendance or involvement of Directors of NCRI since 2011. An example is the apparent absence of consideration of interval cervical cancers despite the fact that, sometimes in the same meeting, they were discussed in relation to breast cancer. The focus of discussions appears to have been a search for changes in incidence rates related to the introduction and consequent hoped-for evidence of the effectiveness of the cervical screening programme. Data which was shared could have been used to raise questions, including temporal data (data that varies over time) on the incidence and stage distribution of invasive cervical cancer. Features of the incidence and stage data produced by NCRI and shared with CervicalCheck and NSS, while not definitively identifying a problem, should have raised alarm bells for further investigation. Specifically:

- The relatively unchanging late stage at diagnosis of women in the screening age group and with a screened status.
- Significant numbers of women in the screening age group were still being diagnosed with cervical cancer who appear not to have been screened.

The first observation should have instigated questions as to why a significant stage shift towards earlier stage cancers being diagnosed in the screening age group was not being observed. The second should have raised questions about coverage and uptake of cervical screening and specifically whether there were inequalities in this. Also, whether this group of women, not detected by screening, had interval cancers detected symptomatically.

To illustrate the findings which could have been discussed, a brief analysis has been undertaken based on tables provided by NCRI showing data on cervical cancers detected between 1994 and 2014 which have been reviewed jointly with CervicalCheck.

	2011 NCRI data	2013 NCRI data
% cancers registered in the screening age band (25-59 years)	39% (106 out of 272)	41% (84 out of 205)
% detected symptomatically	46% (125 out of 272)	45% (93 out of 205)
Classified as 'organised screening'	54% (57 out of 106)	63% (53 out of 84)

There is a suggestion in meeting notes that the method of screen flags on the NCRI database may not completely reflect the actual situation.

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The majority of cervical cancers detected were in the screening age band (25-59 years of age): 205 out of 272 (75%) – the proportion had dropped slightly compared with 79% in 2011.

However, the proportions of stage 3 and 4 in the screening age group were as follows:

	Year					
	2008	2009	2010	2011	2012	2013
Proportion Stage 3 & 4	33.8%	24.0%	26.3%	23.2%	31.9%	27.8%

If this observation had been made it would have warranted further examination of the screening history in these women. From the meeting notes alone, it is not possible to determine whether these observations were made. There is no record of such observations prompting a need for further investigation.

At a teleconference between CervicalCheck, NCRI, and the NSS on 13th January 2017, there was discussion of a cancer audit based in Limerick, which appeared to be using data from colposcopy clinics with screening history. The notes of the teleconference state that the patients can be grouped into: ‘Lapsed attendees; Normal – back for routine tests; Low grade – repeat test; Abnormal – colposcopy’.

This note appears confused and it is not clear whether the audit would adequately assess the quality of the cervical screening programme. There is no discussion noted of missed diagnoses or interval cancers. Discussion followed thereafter that it would be necessary to look at stage, treatment, histological type and follow-up. Also, the numbers unscreened, by local area and deprivation, the method of presentation and the screening history. It was also noted that ‘NCRI could get the screening history from CervicalCheck and CervicalCheck could get a copy of histology from NCRI’. Despite this statement in 2017, there is no evidence from consideration of the available documentation of any action to enable this to information transfer to happen. Moreover, despite results of an audit already being known from June 2016 and discussed between the teams then, there is no documented discussion of interval cancers or potential problems with the screening programme in the meeting notes. Indeed, an email of the 13th January 2017 in preparation for this teleconference contains the agenda as follows:

Updated statistics for Cervical cancer incidence and mortality, for all ages and specific age-groups.

Cancer audit. Cervical cancer in specific groups? E.g. immunosuppressed

Agree ongoing joint research framework

AOB

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Neither the agenda, nor the discussion mention the serious situation of interval cancers in the cervical screening programme, for which data had already been discussed in June 2016. Instead of focusing on the really serious quality assurance issues for which data was critical, the records provided suggest that the focus was on very small rare groups of patients and on research publications.

12.10 Handling of Data and Analytical Requests

It appears that to date NCRI has not had a formal process for reviewing, prioritising or processing data requests. From consideration of the records made available to the Scoping Inquiry, it appears that there seems to be little senior governance or professional oversight of the management and response to data requests. It appears that the review and interpretation of data provided by NCRI is largely undertaken by the external requesters. There have, however, been some requests for projection analyses for cervical cancer to aid the assessment of the potential impact of HPV vaccine or screening. There is also evidence of proposed collaborative work on scientific papers.

12.11 NCRI/NCSS Research Interest

There is evidence of a strong research interest on the impact of cervical screening on incidence, mortality and stage shift and the influence of risk factors such as immunosuppression on risk of cervical cancer. This is, for example, evidenced by an email request from CervicalCheck to NCRI.

As CervicalCheck is currently in its seventh year it is timely to explore a process whereby we can work together to map out a joint research/publication strategy.

The question posed was: Is there any evidence of a shift since 2008 in trends in cervical cancer incidence/mortality/stage/survival when age cohorts are used? Given the average number of cervical cancers diagnosed each year in Ireland, these age cohorts may have produced numbers too small to enable analysis of trends. The use of cancer registry data for research is both legitimate and important. It does, in many quarters, justify the considerable effort that goes into registration. However, the fundamental basics of cancer registration do need to be given the first priority for time and resources. Audit and patient safety are prime examples of the issues that seem to have been given less attention than research, at least according to the paperwork that has been made available to the Scoping Inquiry.

12.12 Clinical, Hospital, and Public Health Input

With respect to their contribution to the cervical screening programme QA, or quality assurance of other cancer related healthcare services, NCRI seems to have very limited clinical or public health input compared to other national cancer registries. This appears to have been matched by very limited public health capacity within

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CervicalCheck. Both organisations are engaged in important public health functions and the apparent lack of sufficient public health expertise within both can only have had a detrimental effect on their interactions and effective functioning.

NCRI is dependent upon receiving information from a range of sources. These sources include CervicalCheck, who run their own mini cancer registration system, but the main source is from hospitals. There is however wide variation in the timeliness of the data provided from hospitals and this hinders both NCRI and the overall cancer control effort, including screening services. The introduction of electronic data capture for cancer data is an imperative for effective cancer registration but has shown little progress in the hospital sector.

12.13 Analysis

NCRI has worked with CervicalCheck to review data on cervical cancer and precancerous lesions since at least 2010. The focus of NCRI's contribution appears to have been in the areas of incidence trends, stage at diagnosis and mortality. Data at the patient level has been transferred from CervicalCheck to NCRI but, until May 2018, no patient level data from NCRI had been requested or transferred in the reverse direction. It is notable that the position is very different between NCRI and BreastCheck, with data transfers taking place in both directions.

It is difficult to understand why if there was a perceived obstacle to the transfer of patient level data from NCRI and CervicalCheck, whether it be a matter of consent or regulation, steps were not taken, at the earliest opportunity, to remove the obstacle. In the absence of access to the data held by NCRI, it is similarly difficult to understand how a properly designed audit of the effectiveness, efficiency and outcomes of the cervical screening programme could have been undertaken by CervicalCheck.

There has been a lack of clarity both of role and governance structure laying out responsibilities for data provision and analysis for the quality assurance of the CervicalCheck programme. This may have led to opportunities being missed to focus on the cases of the women presenting with late stage cancers and their screening histories. This would have been useful both to detect interval cancers and to consider how to increase uptake of cervical screening, as there are still significant numbers of women detected with cancers in the screening age group who have presented symptomatically.

It is unacceptable that there have not been written agreements, contracts, or memoranda of understanding in place between NCRI and the cancer screening services, as well as hospitals. From the records provided to the Scoping Inquiry, this appears to be a complete governance black hole, with the single exception of an agreement of 12 months' duration signed in 2011 between NCRI and CervicalCheck.

12.14 Recommendations

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- 36) NCRI should urgently negotiate and implement data sharing agreements with all major providers and users of registration data. This is necessary in order to meet the requirements of the new EU General Data Protection Regulation but also, and more importantly, represents good governance. Where such an agreement is with an overarching statutory body, such as the HSE, there should also be individual MoUs in place with distinct organisational users of data, such as the cancer screening programmes.
- 37) Timely data is important to assure the effectiveness of both cancer screening and treatment services. This is a patient safety issue. To fulfil its role properly as a cancer registry:
 - (a) NCRI must be given additional support to recruit cancer registration officers and strengthen its public health medicine capacity.
 - (b) The Department of Health and the HSE should commit to make progress on electronic data capture by NCRI from hospitals, and set clear targets for its achievement.
- 38) NCRI should review data definitions related to cervical cancer and CIN (cervical intra-epithelial neoplasia) cases to ensure that the screening flags are meaningful for analysis of the effectiveness of the CervicalCheck programme
- 39) The need to duplicate the collection of patient level details of cervical cancers by both NCRI and CervicalCheck should be reviewed. It is notable that both CervicalCheck and NCRI have identified patients that the other has not. If it is determined that both systems should continue then properly functioning data sharing agreements must be put in place.
- 40) The Department of Health must review the composition of the Board of NCRI in order to ensure more robust governance, in particular in QA, data sharing and patient safety.
- 41) Any future consideration of the governance of the NSS needs to acknowledge, and contribute to the effective oversight of, the specific role played by NCRI in working in conjunction with the cancer screening programmes.
- 42) The Department of Health should work with the Board of NCRI to commission an annual peer review, for at least the next three years, by external cancer registration and cancer control experts. The report of each review and the response to it by NCRI should be forwarded to the Minister for Health.
- 43) NCRI should establish stronger and more regular contacts with external clinical and public health experts to ensure scrutiny of, and advice on, outputs from NCRI so as to enhance the level of its clinical and public health interpretation, importance and impact.
- 44) One of the requirements for the establishment and good management of a screening programme is that health services should be of a good standard to manage those people detected with disease by the screening programme. NCRI, through links with the clinical community, should seek to engage actively in the assessment of the quality of cancer services, comparing these for screen and non-screen detected cases.

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13 Other Screening Programmes

13.1 Background

The terms of reference for the Scoping Inquiry required it to examine the other screening programmes operating under the auspices of the National Screening Service (NSS). The NSS has been accountable to the HSE until recently via its Health and Wellbeing Division for all aspects of the screening programmes, including quality assurance (QA). Each of the other screening programmes (BreastCheck, BowelScreen and Diabetic RetinaScreen) has, like CervicalCheck, its own QA Committee.

13.2 Management and Governance of Quality Assurance

In each of the three screening programmes, the respective QA Committee has responsibility for overseeing implementation of the guidelines for QA in their entirety. This includes reviewing guidelines, and preparing and recommending revisions. The membership of QA Committees is clearly stated and appropriate (having professional, technical and managerial expertise). The Committees have appropriate senior chairs and are active in directing and monitoring QA programmes. The QA Committees are part of the NSS organisational structure, which provides management support.

The BreastCheck QA Committee is accountable, in the first instance to the NSS BreastCheck Executive management team. Likewise, the QA Committee for Colorectal Screening reports to the NSS Colorectal Executive Management Team, and the Diabetic RetinaScreen QA Committee reports to the NSS Diabetic RetinaScreen Executive Management Team. The Head of Screening, National Screening Service, has overall responsibility for quality assurance in all NSS programmes.

However, there is a lack of clarity regarding the overall governance of the QA programmes, and there is no multidisciplinary steering group, or programme advisory board in place for any, or all, of the screening programmes. In the absence of an independent, authoritative board it is doubtful whether the QA Committees can by themselves provide appropriate scrutiny, challenge and support to the screening programmes.

The '*High-level Review of the Overall Functionality and Governance of HSE National Screening Service*' (March 2017) finds that while each of the screening programmes has established QA processes and systems, it draws attention to the need to strengthen high quality, standardised external QA across the programmes. Looking to the UK model for governance of screening services, it considers that,

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*A greater degree of external QA would be desirable and help sustain confidence of the public, professions, policymakers and funders in the high standards of the programmes individually and collectively.*⁹⁵

13.3 Development and Implementation of Quality Assurance Guidelines

For all three screening programmes a thorough professional approach, with appropriate clinical leadership, was adopted for developing their respective QA guidelines and, for Breast Screen and Bowel Screen, there were subsequent revisions. These revisions built on programme experience and developments. For all the programmes, QA guideline development and revisions included use of European guidelines, where available, and engagement with and learning from the respective QA approaches and standards for UK screening programmes. BreastCheck and BowelScreen QA guidelines have been subjected to international (principally UK) external peer review. Development of the Diabetic RetinaScreen was informed by NSS commissioned research on diabetic retinopathy screening programmes internationally, a literature review, and site visits in the UK and Ireland.

In its 2013-2015 report, The National Diabetic Retinal Screening Programme states that:

*To ensure continual adherence to quality assurance across every aspect of the Diabetic RetinaScreen programme, the written and auditable QA standards are updated continually to take into account changes in the environment, whether those changes are technological, operational or reflecting advances in clinical excellence’.*⁹⁶

BreastCheck takes part in external accreditation, having had three external reviews since the programme was inaugurated; most recently by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services, EUREF. EUREF has only awarded six screening programmes accreditation since 2009, only two of which have been awarded the highest quality of accreditation, which is a category 4 reference centre accreditation, and BreastCheck is one of those two.

In relation to BowelScreen, an investigation of a safety incident at Wexford Hospital was subsequently subject to external review.⁹⁷ The external review concluded that:

- 1) *The look back process was carried out in a timely and efficient manner, and to the highest possible standards.*
- 2) *There were missed early opportunities to identify shortcomings in the performance of the colonoscopist responsible for the incident, but that there were significant mitigating circumstances surrounding this.*

⁹⁵ Prospectus. High-level Review of the Overall Functionality and Governance of HSE National Screening Service. HSE. March 2017.

⁹⁶ *Diabetic RetinaScreen Programme Report 2013-2015*. The National Diabetic Retinal Screening Programme. p10.

⁹⁷ Safety Incident Management Team Report for NIMLT Case 50796, Final Report 17th January 2017.

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- 3) *Current QA governance arrangements between BowelScreen and its provider units are appropriate.*⁹⁸

The Safety Incident Management Team report for this incident, combined with the conclusions of the external reviewer, provide an indication of the appropriateness and high standards being achieved and maintained by the QA function of BowelScreen. Valuable learning from this incident will strengthen the BowelScreen programme and aspects of the learning would be of benefit to all of the screening programmes. One of the recommendations of the external reviewer was;

*That there should be a regular programme of revision of Quality Assurance Guidelines and the tolerance limits set by these Guidelines.*⁴

This re-emphasises the importance of ensuring the regular review of QA guidelines that each of the three screening programmes commit to, is undertaken in a timely manner.

From the expertise available on and to the QA Committees, and the process adopted in designing the programmes and selecting standards it is safe to conclude, firstly, that the standards in each of the different components of the screening programme are appropriate, as are cohort definitions etc. and, secondly, that the technical, managerial and clinical governance structures for implementing, monitoring and reviewing the standards are sound. However, there is considerable variation between the QA guidelines in terms of their comprehensiveness and level of detail. For example:

- a) Standards for introductory and continuing staff training are not consistently set out for all of the programmes;
- b) Standards for performance monitoring, including identification of underperformance, appropriate corrective action and/or suspension for procedures where technical standards are not being met;
- c) Standards for identifying clinical under-performance, could benefit from a uniform approach across programmes, and;
- d) Standards related to procedures and processes for reporting failure to meet technical standards, achieving acceptable levels of clinical performance, and tackling associated risks to the appropriate management and governance level in the system could be more explicit.

Being mindful of the significant technical differences in the various screening programmes and the necessity of QA Guidelines being developed to meet the specific needs of each screening programme there could, nevertheless, be a great deal of benefit if there were some shared methodology that all QA guidelines should meet. A similar point is made by the *High-level Review of the Overall Functionality and Governance of HSE National Screening Service, 2017*, which contains a number

⁹⁸

Steele RJC. External Review of NIMLT case 50796. HSE. January 2018. p2.

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of proposals to facilitate cross programme learning (in addition to a greater degree of external QA) for continuous quality improvement.

The membership of the QA Committees should be refreshed at regular intervals so that there are always new pairs of eyes looking at the important quality issues.

13.4 Clinical Audit

The BreastCheck QA guidelines from 2008 draw attention to the importance of ongoing clinical audits in ensuring all health professionals engaged in screening - radiographers, radiologists, pathologists, surgeons and nurses – are,

...able to adapt easily to the ever-changing technology without losing sight of the patients.⁹⁹

The same guidelines made it clear that the clinical audit was seen to be important in meeting accreditation standards. For nurses, participation in clinical audit at unit level is one of the minimum standard requirements.

BowelScreen QA guidelines likewise specify that each screening centre should carry out a rolling programme of clinical audits of quality standards (e.g. of caecal intubation rate and adherence to surveillance guidelines) in accordance with periodic guidance issued by the BowelScreen programme. The 2017 guidelines state that,

The responsibility to adhere to agreed standards rests primarily with the individual endoscopists. Supported by the hospital, the clinical lead ensures audits are performed at least quarterly. Identified under-performance is addressed locally, and overall performance data are returned to BowelScreen at agreed intervals. The NSS reserves the right to carry out additional audits to verify high clinical standards.¹⁰⁰

Diabetic RetinaScreen QA Guidelines do not refer to clinical audits.

In its *Strategy 2017 – 2020* the National Office for Clinical Audit (NOCA) commits to,

Advocate for local clinical audit education and training to support quality improvement.¹⁰¹

This approach should benefit local clinical audits undertaken in the context of the several screening programmes. To date screening programmes have not been included in the national clinical audit programme. However, NOCA is committed to

⁹⁹ Guidelines for Quality Assurance in Mammography Screening. Third Edition. The National Cancer Screening Service Board. 2008. p13.

¹⁰⁰ Guidelines for Quality Assurance in Colorectal Screening. National Screening Service. 2017. p34.

¹⁰¹ NOCA Strategy 2017-2020. The National Office of Clinical Audit. p26.

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identifying newly prioritised national clinical audits as part of its current strategy and this could include clinical aspects of screening programmes.

13.5 Open Disclosure

All of the screening programmes have a screening charter. The one quoted below is the BreastCheck Women's Charter and among its standards and commitments to patients are:

- *To tell you sensitively and with honesty*
- *To fully explain the treatment available to you*
- *To encourage you to share in decision-making about your treatment*
- *To include your partner, friend or relative in any discussions if you wish*
- *To give you the right to refuse treatment, obtain a second opinion or choose alternative treatment, without prejudice to your beliefs or chosen treatment*
- *To arrange for you to be admitted for treatment by specialised trained staff within three weeks of diagnosis*
- *To provide support from a Breast Care Nurse before and during treatment*
- *To provide you with information about local and national cancer support groups and self- help groups*¹⁰²

However, neither in the charters, elsewhere in the QA guidelines or on the websites is there reference to the requirements on open disclosure, such as they are, in the HSR policy and HSE/SCA guidelines.

From these documentary sources and discussions with key individuals, it appears that the NSS did not require the QA Committees of the screening programmes to consider adoption of appropriate QA standards relating to HSE 'open disclosure' guidance, including awareness raising or training. It also appears that the QA Committees did not do so on their own initiatives. From a number of sources, it seems that it is only recently (in light of the CervicalCheck concerns) that 'open disclosure' became a live issue for the other screening programmes.

In evidence to the Joint Oireachtas Committee on Health (23rd May 2018) it was confirmed by the clinical lead for BreastCheck that the HSE proposes an open disclosure policy is implemented for BreastCheck in 2018. However, while BreastCheck has not formally introduced the HSE open disclosure policy, it appears from a number of sources, including witness evidence to the Joint Oireachtas Health

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BreastCheck Women's Charter. BreastCheck. QP-010 Rev07. <https://www.breastcheck.ie/sites/default/files/bcheck/documents/breastcheck-womens-charter.pdf>

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Committee, that the BreastCheck programme has a culture of open and supportive communication with its clients in relation to all aspects of their care and experience.

A similar situation to BreastCheck appears to pertain with respect to open disclosure and the BowelScreen programme. This is evidenced by the positive conclusion of the previously mentioned external review into the Wexford incident.

Every effort was made to identify and communicate with the patients before public communication was commenced. Following media publicity, the HSE information line was used to handle questions from the general public. The original patients whose cases initiated the look back received open disclosure and have been provided with copies of the systems analysis reports. On identification of each new case of colorectal cancer identified by the look back process, contact with the patient and their family was made to invite them for formal open disclosure meetings in WGH. This review concludes that disclosure was handled in an appropriate and timely manner.¹⁰³

13.6 Interval Cancers

Interval cancers are cancers that arise after a negative screening and before the next scheduled screening round. There are international standards for interval cancer rates in screening programmes, and the rate in any particular programme is an important measure of the quality of the programme.

The BreastCheck QA Guidelines include a comprehensive and detailed description of how interval cancers are to be managed. In her evidence to the Joint Oireachtas Committee on Health (23rd May 2018) the national clinical lead for BreastCheck provided a succinct account of how BreastCheck, in collaboration with the National Cancer Registry, identifies and calculates its interval cancers rate, emphasising that,

...the interval cancer reviews are not patient-centered but programme-centered in order to determine the interval cancer rates.¹⁰⁴

There is, however, the option for a woman to ask for a retrospective review of previous mammograms.

...any woman diagnosed with an interval breast cancer can request a review of her screening mammogram, or her clinician can do so on her behalf. That review happens in real time at the earliest possible convenience. It is performed by two consultant radiologists who were not

¹⁰³ Steele RJC. External Review of NIMLT case 50796. HSE. January 2018. p21.

¹⁰⁴ https://data.oireachtas.ie/ie/oireachtas/debateRecord/joint_committee_on_health/2018-05-23/debate/mul@/main.pdf p36.

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*involved in reporting the screening mammogram. The information is then communicated to the patient.*¹⁰⁵

The Committee was told by another expert witness, a Professor of Surgery and leading authority in the field of breast cancer surgery, that:

*There is an excellent process in the screening programme whereby if a woman has had a screening mammogram, we contact the service to say that she has been diagnosed. The service will offer to sit down with her and go through the mammograms. Frequently, it may not have been seen on the previous mammogram. That is the nature of this test. There is real openness there.*¹⁰⁶

An interval colorectal cancer (CRC) is one diagnosed following a negative screening test, that is the self-administered Faecal Immunochemical Test (FIT), before the next screening FIT, or within three years of the client going over the eligible age. A post-colonoscopy colorectal cancer (PCCRC) is the diagnosis of a CRC within three years of a negative screening colonoscopy. Likewise, a CRC diagnosed at the next screening colonoscopy is considered to be a PCCRC if it occurs within three years of the most recent colonoscopy. As with the interval cancer rate in BreastCheck, the PCCRC rate is a key quality measure of colorectal cancer screening programmes. Available evidence indicates that PCCRC rates vary from 2.5 per cent to 8.6 per cent. It will be a number of years before the PCCRC rate can be calculated for the BowelScreen programme, but the BowelScreen QA Guidelines anticipate that for the BowelScreen programme the PCCRC rate would be closer to the lower range.

13.7 Linkages to the National Cancer Registry Ireland

BreastCheck QA Guidelines state that 'breast screening data and NCRI data need to be combined to determine the screening status of the women at the time of diagnosis'. While this has not been formally acted on, exchanges of information take place as part of the audit of interval breast cancers. In evidence to the Joint Oireachtas Health Committee (referred to above) the clinical lead for BreastCheck confirmed that,

*BreastCheck is informed of all cancers by the National Cancer Registry. BreastCheck then determines if a woman has attended for screening and validates if it was within the past two years and if at the time of diagnosis the cancer was invasive. If these criteria are fulfilled, it is deemed to be an interval cancer and included in the rates published in our literature.*¹⁰⁷

¹⁰⁵ Ibid p34.

¹⁰⁶ Ibid p36.

¹⁰⁷ Ibid p34.

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BowelScreen QA guidelines do not address the link to NCRI. However, the report on an external review of the Wexford incidents confirms that a linkage between the Registry and BowelScreen exists for the reporting of interval cancers. The report also states:

*It appears that, prior to this incident, there was no formal method of identifying post colonoscopy cases despite there being a requirement for them to be reported.*¹⁰⁸

At the time of the external review of the Wexford incident, there was no process in place to match cases known to NCRI, which receives information and histological confirmed cancers within weeks of diagnosis, to BowelScreen cases. This would require lists of BowelScreen participants to be sent to NCRI.

These findings reinforce the findings in the section of this report, specifically on cancer registration, that comprehensive, adequate and robust formal arrangements for the exchange of information between the screening programmes and NCRI have not yet been put in place.

13.8 Analysis

The professional and technical resources of the three QA programmes are of an appropriately high standard. Operational and mid-level management, and regional and national clinical direction of the programmes appear to be sound. Commissioning arrangements, monitoring and performance management of provider contracts at the different levels in the screening services of the QA programmes also appear to be acceptable. However, the overall governance arrangements for the QA programmes are not sufficiently robust.

The arrangements for the selection and revision of QA standards and the respective QA guidelines overall are in line with international (European including UK) guidance and good practice. But not all of the programmes are sufficiently specific in setting standards for some elements of the screening programmes e.g. introductory and continuing staff training.

Until recently, the implications of HSE open disclosure policy for the QA of the screening programmes have not been given sufficient consideration. Nevertheless, there is evidence that both BreastCheck and BowelScreen relate to their clients when adverse incidents are identified in an open and sensitive manner. While there is an exchange of information between the cancer screening programmes and the National Cancer Registry this is occurring in the absence of a proper policy, formal management arrangements or sound governance oversight, as is noted elsewhere in this report.

¹⁰⁸

Steele RJC. External Review of NIMLT case 50796. HSE. January 2018. p12.

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13.9 Recommendations

- 45) Considering the clinical and technical differences that characterise the different screening programmes, NSS needs to advance its thinking on cross programme learning, external QA, and governance oversight of the QA programmes.
- 46) The composition and duration of appointments for all QA Committees should be reviewed, in conjunction with emerging clinical advisory committee structures.
- 47) The QA Committees should review and confirm the adequacy of the arrangements within their respective screening programmes for introductory training and continuing staff development, as well as the arrangements at all levels in the quality system for identifying and appropriately responding to inadequate technical or clinical performance.
- 48) NSS should consider, with external assistance, the relevance of the HSE policy on 'Open Disclosure' as it develops in light of this Scoping Inquiry, for all of its screening programmes.

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14 Resolution

“So, am I just a number? Did my document/life get lost in the system? Does anyone care?”

14.1 Background

It will, I hope, be obvious from a reading of the report, particularly the sections that deal with Open Disclosure, that an injustice was done to this group of women. On top of their diagnosis of cervical cancer, and all that has meant for them and their families, they have had to deal with a flawed approach to the disclosure of audit findings that called into question the initial laboratory readings of cervical smears from before, sometimes long before, they were diagnosed. The process by which most of them were ultimately made aware of this information, compounded the problem.

While some cases have proceeded through the legal system, and the Scoping Inquiry is aware that there are many more engaged in the legal process at present, it is clear from having met many women and families that they are seeking more than just a financial settlement. Many expressed the view that they only undertook legal action because of their frustration with the system. In general, and in common with many of those who have been traumatised within health services elsewhere, they are seeking three main outcomes from the work of this Scoping Inquiry and the various efforts to resolve the serious issues that trouble them:

- To be told what happened and why (the truth);
- For someone who was involved to say they are sorry, and mean it;
- To be assured that this won't happen again to anyone else.

Unfortunately, for many women the only route that is open to them is legal action for medical negligence. The legal system in Ireland, as far as medical negligence is concerned, is universally regarded as deeply flawed and in desperate need of reform. It can only be hoped that one possible outcome of these serious screening issues is that some of the necessary reforms are introduced. However, I do not believe that the currently available legal remedies are capable of resolving the deep hurt, anguish and resentment felt by many of the women and families involved. That would require something very different.

“Tell us the truth”

“We want processes, we want procedures, we want action””

The Government has appointed Mr Justice Charles Meenan to recommend how cases can be resolved in a sensitive and timely manner, outside the usual adversarial court system. In my progress report, I recommended that there should be

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a process established enabling structured conversations with every woman affected who wishes to have her experience documented, or with appropriate surviving family members in cases where the patient has died, if they so wish. Over the summer it has not been possible to make progress on this recommendation, but I still believe it is valid and would potentially assist in achieving resolution. I have asked Justice Meenan to give consideration to its potential value and how it might operate.

14.2 Grace and Compassion

What has been sadly lacking in this whole episode, and what could assist in its resolution is what has, I believe, been very accurately described as ‘grace and compassion’. In a landmark judgement from the Constitutional Court of South Africa about landowner and occupier rights, Justice Albie Sachs wrote of ‘infusing grace and compassion into the formal structures of the law’.¹⁰⁹ His approach suggests a way in which mediation could infuse all our systems, legal, political and administrative with grace and compassion. Although a system of mediation in court cases is already part of the legal process it rarely, if ever, is accessed unless a court case has been brought in the first place. As Turlough O’Donnell SC, a former Chair of the Bar Council, has written:

*The lesson for us all whether in administration or in the legal system, is that cost effectiveness and efficiency are not enough. There is room in our systems for more grace and compassion and we should dare to believe in the possibility of achieving that.*¹¹⁰

This should be regarded as not alone a reasonable but a desirable expectation; and it is easy to see how things could have been handled very differently. Of course, most of the physical effects of cervical cancers cannot be reversed and some women have died and left behind grieving families. It is however, I believe, not too late to try and repair some of the other damage caused and help achieve the three desired outcomes listed above.

14.3 What Happened and Why?

In theory this should be easy to achieve. In practice, for all the reasons spelt out in the various sections of this report, it is complex. Nonetheless, this report attempts to provide as much clarity on the key issues as it has been possible to assemble. The very important work of the Royal College of Obstetricians and Gynaecologists (RCOG) review will provide a further vital part of the jigsaw.

¹⁰⁹ 2005(1) SA 217 <http://www.saflii.org/za/cases/ZACC/2004/7.html>

¹¹⁰ O’Donnell T. Reflections on the role of mediation in resolution of disputes in Law and Government: *A Tribute to Rory Brady*. Eds. Blathna R. et al. Round Hall. 2014. p124-36.

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14.4 Someone Who Was Involved to Say They Are Sorry, and Mean It

At the heart of this issue lies the willingness and strength to speak the truth, as well as the willingness and ability to listen when others speak it. There are people who can, and have, spoken on behalf of organisations involved and who have said sorry. But that does not deal with the resentment that is felt by many women at the way clinicians interacted with them. As noted elsewhere in the report this has, in some cases, led to a serious loss of confidence between patient and doctor.

I know from talking with many of the women and families involved that they are angry about things being kept from them: things that they believe they had an absolute right to know, if they so wished. I know from talking with some of the doctors involved, that they feel that they were put in a very difficult position that was none of their making, by an organisation of which they did not feel part. Given this background it is little wonder that the doctor patient relationship was, in some cases, shattered.

I do not believe that this is beyond repair. The Quirke report into the Magdalene Laundries recommended that a process of restoration should be facilitated where nuns from the relevant religious orders and former residents of the Laundries, who wished to do so, should be able to meet and discuss what took place. Although this proposal was not acted upon, it was soundly based. In the case of CervicalCheck, I can see no reason why a facilitated and voluntary meeting could not be held between a woman and the relevant doctor to discuss what happened. The speaking of, and listening to the truth, on both sides might well be successful.

“My initial feelings where “Thank God I am alive to take the call”. But as the days and weeks went by, I thought about nothing else, my feelings changed to what I can only describe as anger and a deep feeling of neglect by our health system”.

14.5 Assurance That This Won't Happen Again to Anyone Else

Many, if not all, of the recommendations in this Scoping Inquiry are aimed at ensuring that nothing like this can happen again. But whilst structures, staffing, protocols and policies can address many deficiencies, others are more difficult to transform. It is clear from the experiences of the women and their families that a major culture shift is needed in respect of Open Disclosure amongst health professionals. I believe there is a willingness to move forward and committed leadership amongst the medical profession could make an enormous difference. Just as I have, as a person, been deeply moved by the fortitude, dignity and incisiveness of those most deeply affected by this episode, I have, as a doctor, been humbled and ashamed that it should have happened in the first place. I suggest that the leaders of the medical profession in Ireland should be encouraged to meet face to face with those most affected, so that they too can hear from patients how they feel they were dealt with by the system, and by the medical profession. A dialogue about how the profession is

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changing and how that change can be supported and encouraged would be of undoubted value and again is a restorative process.

14.6 Recommendations

- 49) The Department of Health should consult with interested parties as to how women and families who wish to, can be facilitated in meeting with the clinician who was involved with their care and/or disclosure.
- 50) The Department of Health should encourage and facilitate (but not necessarily participate in) a meeting involving the presidents of the Medical Council, the Royal Colleges and their faculties, leaders of other leading medical organisations and representatives of the women and families involved with the cervical screening problems.

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15 Summary of Recommendations

Method of Approach

- 1) The Department of Health and the HSE should revise their policies in respect of document management. This should ensure that good quality records are created and maintained which are authentic, reliable, and complete in searchable format. They should be protected and preserved to support future actions and ensure current and future accountability.

Listening to the Voices of the Women and Families Affected

- 2) The Minister for Health should give consideration to how women's health issues can be given more consistent, expert and committed attention within the health system and the Department of Health.
- 3) The Department of Health should examine the current arrangements for patients to have access to their hospital medical records so that such access can be achieved in a timely and respectful way.

CervicalCheck – Organisation and Governance

- 4) The Minister for Health should consider seriously the appointment of two patient advocates to the proposed new Board for the HSE.
- 5) A National Screening Committee should be constituted to advise the Department of Health and the Minister on all new proposals for screening and revisions to current programmes.
- 6) The NSS, whatever its location within the HSE, should be able to access senior levels of the organisation and be located close to strategically and logically linked services.
- 7) A far greater component of professional and public health expertise should be deployed across the screening services, not as external advisors but with significant roles within the screening programmes.
- 8) The implementation of new governance arrangements for the HSE should include a substantial revision to the organisational approach to risk management and its reporting.

CervicalCheck – Laboratory Services

- 9) CervicalCheck should revise its programme standards to clarify what is mandatory, and to clarify the level of reliance on external accreditation processes. This is particularly important in respect of laboratory service providers in other jurisdictions.
- 10) As a priority all providers should fully implement a single agreed terminology for the reporting of results and ensure that criteria for defining the different grades of abnormality are consistently applied.

Scoping Inquiry into the CervicalCheck Screening Programme

- 11) Based on revised programme standards, a specification for a new and more robust quality assurance procedure should be documented and form part of the contract for services with cytology providers.
- 12) CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.
- 13) CervicalCheck should document which organisation (e.g. CervicalCheck, HSE, Providers) has responsibility for pursuing issues of continued non-compliance and the consequences thereof. An advisory group of cytopathologists and other laboratory based staff should be established to advise on this process, and this should include input from those who work for non-State providers.
- 14) CervicalCheck should collate and publish annual data on reporting rates for all categories broken down by provider.
- 15) In order to obtain comparable data CervicalCheck should amend data specifications to exclude samples taken from colposcopy, and analyse and publish all performance statistics on samples taken in primary care, or equivalent, only.
- 16) When this change to comparable data is made further epidemiological investigation is required to establish whether the differential rates of abnormality persist and, if so, to what extent they can be attributed to underlying population differences.
- 17) The different rates of sensitivity for ASCUS+ identified by second screen at each provider require further investigation by CervicalCheck.
- 18) The different inadequate rates are not a cause for immediate concern. The Scoping Inquiry recommends that the findings of the English health technology assessment (HTA) study referenced in Appendix 1 are implemented across all providers to try to obtain more consistency.

Procurement of Laboratory Services

- 19) Winning proposals should be appended to the relevant contract and not destroyed until at least one year following the termination of the contract (and any extension thereof).
- 20) A system should be put in place for proactive contract governance in order to safeguard the future of the service and the relationship of the service with the market place.
- 21) Procurement processes for external laboratory services should be designed to test the market at reasonable intervals (e.g. every four years), to ensure that CervicalCheck does not become overly reliant on a small number of incumbent suppliers, and to ensure that innovative approaches and added value can be formally captured within the procurement process.
- 22) CervicalCheck should ensure that its procurement approach maintains a balanced focus on qualitative factors, supplier experience, and innovation, alongside cost considerations.

Scoping Inquiry into the CervicalCheck Screening Programme

- 23) CervicalCheck should ensure that future procurements incorporate measures to test performance in the current contract.
- 24) External professional assistance should be sought in the construction of any future RFP, and the evaluation of proposals in order to ensure that best practices developed across the public sector since 2012 are incorporated into key areas such as development of RFP documents, supplier briefings, construction of award criteria, construction of evaluation panels, establishment of governance and continuous improvement programmes, etc.
- 25) Assurances should be sought with respect to the capability to deliver the service as specified and without material change. Where change is possible, robust change management procedures, which include approval by the procuring authority, should be defined.

Auditing Cervical Screening

- 26) Audits should continue to be an important component of cervical screening as this complies with all good clinical practice. Common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.
- 27) There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services.

Open Disclosure and the HSE

- 28) The HSE's open disclosure policy and HSE/SCA guidelines should be revised as a matter of urgency. The revised policies must reflect the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and, in particular, their right to be informed about any failings in that care process, however and whenever they may arise. The revision process should be overseen by a working party or committee with a minimum of two patient advocates amongst its members.
- 29) The option of a decision not to disclose an error or mishap to a patient must only be available in a very limited number of well-defined and explicit circumstances, such as incapacity. Each and every proposed decision not to disclose must be subject to external scrutiny and this scrutiny process must involve a minimum of two independent patient advocates.
- 30) A detailed implementation programme must be developed that ensures the principles and practice of open disclosure are well understood across the health service. In particular, medical staff must be required, as a condition of employment, to complete training in open disclosure.
- 31) A governance framework for open disclosure must be put in place that includes evaluation and audit.
- 32) An annual report on the operation of open disclosure must be presented in public session to the full Board that is to be appointed to govern the HSE.

Scoping Inquiry into the CervicalCheck Screening Programme

Open Disclosure and the Medical Council

- 33) The Department of Health should enter into discussions with the Medical Council with the aim of strengthening the guide for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure.

Open Disclosure and CervicalCheck

- 34) A statutory duty of candour must be placed both on individual healthcare professionals and on the organisations for which they work.
- 35) This duty of candour should extend to the individual professional-patient relationship.

Cancer Registration

- 36) NCRI should urgently negotiate and implement data sharing agreements with all major providers and users of registration data. This is necessary in order to meet the requirements of the new EU General Data Protection Regulation but also, and more importantly, represents good governance. Where such an agreement is with an overarching statutory body, such as the HSE, there should also be individual MoUs in place with distinct organisational users of data, such as the cancer screening programmes.
- 37) Timely data is important to assure the effectiveness of both cancer screening and treatment services. This is a patient safety issue. To fulfil its role properly as a cancer registry:
- (a) NCRI must be given additional support to recruit cancer registration officers and strengthen its public health medicine capacity.
 - (b) The Department of Health and the HSE should commit to make progress on electronic data capture by NCRI from hospitals, and set clear targets for its achievement.
- 38) NCRI should review data definitions related to cervical cancer and CIN (cervical intra-epithelial neoplasia) cases to ensure that the screening flags are meaningful for analysis of the effectiveness of the CervicalCheck programme
- 39) The need to duplicate the collection of patient level details of cervical cancers by both NCRI and CervicalCheck should be reviewed. It is notable that both CervicalCheck and NCRI have identified patients that the other has not. If it is determined that both systems should continue then properly functioning data sharing agreements must be put in place.
- 40) The Department of Health must review the composition of the Board of NCRI in order to ensure more robust governance, in particular in QA, data sharing and patient safety.
- 41) Any future consideration of the governance of the NSS needs to acknowledge, and contribute to the effective oversight of, the specific role played by NCRI in working in conjunction with the cancer screening programmes.

Scoping Inquiry into the CervicalCheck Screening Programme

- 42) The Department of Health should work with the Board of NCRI to commission an annual peer review, for at least the next three years, by external cancer registration and cancer control experts. The report of each review and the response to it by NCRI should be forwarded to the Minister for Health.
- 43) NCRI should establish stronger and more regular contacts with external clinical and public health experts to ensure scrutiny of, and advice on, outputs from NCRI so as to enhance the level of its clinical and public health interpretation, importance and impact.
- 44) One of the requirements for the establishment and good management of a screening programme is that health services should be of a good standard to manage those people detected with disease by the screening programme. NCRI, through links with the clinical community, should seek to engage actively in the assessment of the quality of cancer services, comparing these for screen and non-screen detected cases.

Other Screening Programmes

- 45) Considering the clinical and technical differences that characterise the different screening programmes, NSS needs to advance its thinking on cross programme learning, external QA, and governance oversight of the QA programmes.
- 46) The composition and duration of appointments for all QA Committees should be reviewed, in conjunction with emerging clinical advisory committee structures.
- 47) The QA Committees should review and confirm the adequacy of the arrangements within their respective screening programmes for introductory training and continuing staff development, as well as the arrangements at all levels in the quality system for identifying and appropriately responding to inadequate technical or clinical performance.
- 48) NSS should consider, with external assistance, the relevance of the HSE policy on 'Open Disclosure' as it develops in light of this Scoping Inquiry, for all of its screening programmes.

Resolution

- 49) The Department of Health should consult with interested parties as to how women and families who wish to, can be facilitated in meeting with the clinician who was involved with their care and/or disclosure.
- 50) The Department of Health should encourage and facilitate (but not necessarily participate in) a meeting involving the presidents of the Medical Council, the Royal Colleges and their faculties, leaders of other leading medical organisations and representatives of the women and families involved with the cervical screening problems.

Scoping Inquiry into the CervicalCheck Screening Programme

Appendix 1: Cervical Screening Data

Notes of Data Collection, Analysis and Reporting

It is important to note that the Scoping Inquiry found that the collection, analysis and reporting of data by CervicalCheck over the course of the programme has been inconsistent. It was difficult to access and analyse basic information on the reporting rates provided by laboratories, and this was mostly done using reports provided by the laboratories themselves, as opposed to data collected by CervicalCheck itself.

Notes on Terminology, Classification and Management

CervicalCheck uses the Bethesda System (TBS) for cervical cytology classification. TBS is widely used internationally (including in the USA, hence its use by CervicalCheck) and is supported by a range of guidance documents, training resources and publications. CervicalCheck used a conversion table to convert to its own classification (P codes). Although this is a direct substitution, this report uses TBS codes only.

TBS codes are roughly translatable to the British Society for Clinical Cytology (BSCC) classification used in the UK which is useful for comparison.

Management is defined for all codes:

- After the introduction of HPV triage in May 2015, all low grade abnormalities (ASCUS, LSIL, AGUS and AGC) were managed in the same way, with HPV testing and referral to colposcopy where a positive result was returned.
- High grade abnormalities (which includes ASC-H and glandular abnormalities other than those listed above) have always been managed by referral to colposcopy.

Prior to 2015, there are likely to have been differences in management of ASCUS and LSIL; however, the Scoping Inquiry has been unable to identify documentation to support this.

Of all the reporting categories, ASCUS has the lowest intra-observer agreement. TBS has a lower threshold for ASCUS than the BSCC classification. In US practice, ASCUS will be used in a significant number of cases where the changes are physiological.

LSIL is slightly more reproducible, especially as this includes all cells showing Koilocytic change, which is easy to identify and indicates morphological evidence of HPV infection.

High Grade changes (HSIL) are generally very reproducible as high grade, though agreement between High Grade Moderate and High Grade Severe is less robust.

The category of ASC-H (Abnormal squamous cells of uncertain significance-high grade) was abandoned in the UK in 2008 because all published studies showed an outcome which was very close to that seen for HSIL. It is persistently used in TBS. In view of this, outcomes after ASC-H are as expected.

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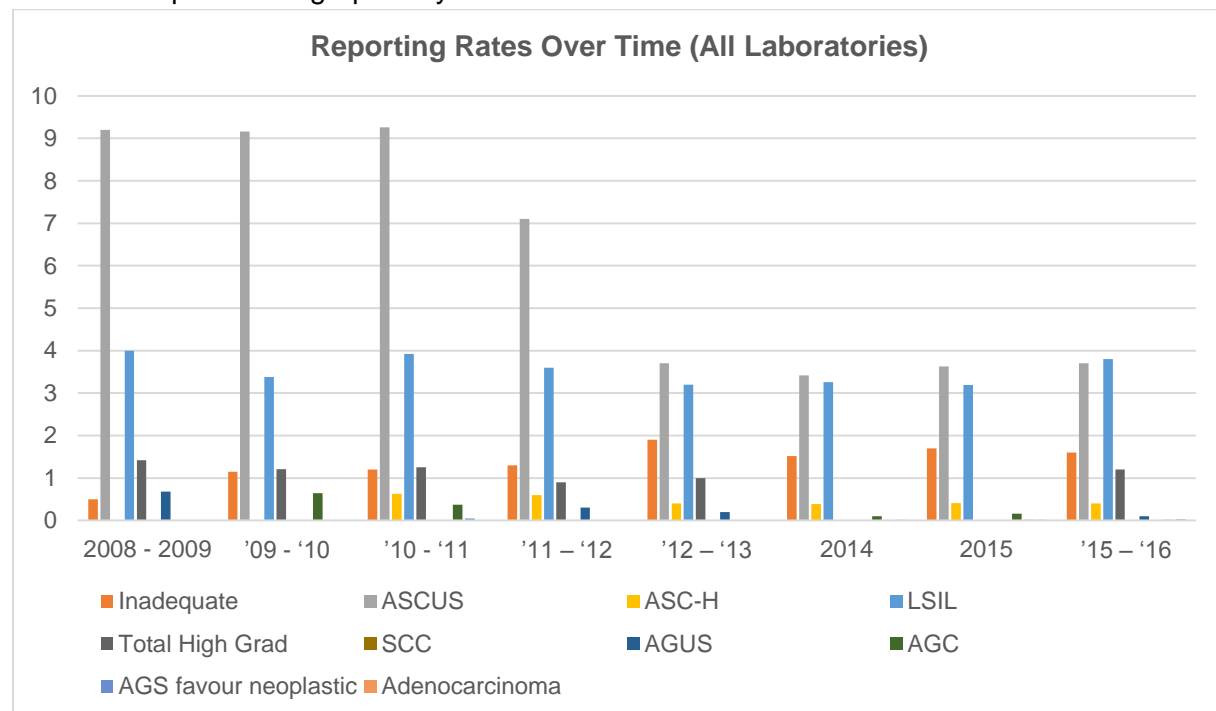
Cytology Category Reporting

The table below shows a partial summary of reporting rates for all result categories for all women screened within the CervicalCheck programme.

Year:	08-09	09-10	10-11	11-12	12-13	2014	2015	15-16
Total smears	28,5012							
Inadequate	0.5	1.15	1.2	1.3	1.9	1.52	1.7	1.6
ASCUS	9.2	9.16	9.26	7.1	3.7	3.42	3.63	3.7
ASC-H		0	0.63	0.6	0.4	0.39	0.41	0.4
LSIL	4	3.38	3.92	3.6	3.2	3.26	3.19	3.8
HSIL (mod)	0.9	0.57	0.58	0.5	0.5	0.56	0.51	0.6
HSIL (Sev)	0.52	0.64	0.67	0.4	0.5	*	*	0.6
Total High Grad	1.42	1.21	1.25	0.9	1.0	0.56 *	0.51 *	1.2
SCC	0.01		0.01	0	0.01	0.01	0.01	0.01
AGUS	0.68			0.3	0.2			0.1
AGC	0.01	0.64	0.37			0.1	0.16	
AGS favour neoplastic		0	0.05			0.01	0.02	0.02
Adenocarcinoma		0.01	0.01	0		0.02	0.02	0.03

**This may represent an error in the data – probably only one category of HG is included.*

This data is presented graphically below:



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Some data on specificity of cytology results identified is, again, incomplete.

Year:	09-10	10-11	11-12	2013	2014	2015	15-16
PPV HG	86.4	77	79	75.6			
PPV LG	95.1	68					
APV			26.6	28.7			
TPV			46.5	45.8			
RV			2.15	2.18			

Notes and comments

- There have been terminology changes, particularly concerning the reporting of low grade glandular abnormalities (AGUS, AGC, AGC favour neoplastic).
- The 'Borderline' category for glandular cells was initially AGUS (Abnormal glandular cells of uncertain significance) but was then changed in TBS to AGS (Abnormal glandular cells). Both of these categories have at times been very frequently reported, with rates up to 0.68% in the early days of the programme. In UK practice these abnormalities would be very rare – less than 0.1% in current practice, so this level is high, and to a lesser extent has remained high in the US reporting labs. This represents a dilemma for colposcopy, as glandular lesions can be very difficult to diagnose or exclude at colposcopy, therefore an abnormal glandular cytology result may result in overtreatment or intensive surveillance. It is likely that concerns about this resulted in all such reports being reviewed at the Coombe Women & Infants University Hospital (CWIUH) prior to the QA visit in 2014, which recommended this process should stop. However, even subsequent to this the CWIUH reporting rate remained aligned with UK practice with similar but higher levels reported in the other two providers.
- The initial Inadequate rate of 0.5 % is very low. It subsequently rose to a steady rate of between 1% and 2%. This is still low by UK standards, but not excessively so. The likely explanation is that Quest was using US criteria for adequacy, which only required 5000 cells/slide, as opposed to the UK criteria which was at the time requiring 15 000. It seems likely that an intervention was carried out which resulted in the rate increasing. However, note from data below that Quest still had a lower inadequate rate than other providers in 2015. It should however be noted that subsequent research in the UK (Health technology assessment (Winchester, England) 19(22):1-64 March 2015) has defined that 5000 is adequate to detect abnormalities. Therefore, this is unlikely to represent a risk.
- ASCUS rates were very high up until 2011-12. Clearly some intervention occurred at this point, but the Scoping Inquiry has been unable to identify any documentation to explain this. It is highly unlikely that it is entirely due to a change in actual disease incidence. However, the drop does correspond to the second round of screening for younger women, which may have contributed to this somewhat. Subsequently the ASCUS rates have dropped and are now stable and in line with the UK.
- ASCUS and LSIL combined were also high, though the LSIL rate itself is reasonably constant. The rate now is in line with UK practice. These two categories are often

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combined in analysis as low grade disease. The high rate prior to 2012 would have resulted in significant harm to women in terms of anxiety and unnecessary repeat tests and colposcopy referrals.

- Since 2015 HPV triage of all low grade disease has been performed. No data was submitted on HPV positivity rates – this would give a good indication of the specificity of a diagnosis of ASCUS and LSIL and could easily be compared to the English pilot data, which is published.
- ASC-H is not used in the UK. The rate for Irish women has been fairly constant and is in keeping with US experience. Many of these women– published studies suggest around 60%- will have high grade disease.
- The total high grade rate at the beginning of the programme was 1.42%. It later fell significantly but even in 2015-16 remained high by UK standards at 1.2% (or 1.6% if ASC-H is included). It is to be expected that the true incidence of high grade CIN would be higher than in the UK during the prevalent round of screening. Because of uptake of less than 100%, and the fact that women may respond late to invitation, diluting the cohorts, this gradually falling rate is as expected. It would appear to represent genuine disease because the PPV remains reasonably high.
- PPV for high grade disease started very high and came down, though still reasonable at around 75%. There does not appear to be documentary evidence of yearly overall PPV in the documents submitted, though there are references to it and it was probably monitored. Note that laboratories felt that histology data was not returned to them in an acceptable timeframe. Delays in adding histology outcomes to the system result in a PPV which differs on different dates, which is unhelpful. There is some useful differential PPV data included below. PPV is a composite measure – it requires specific cytology, but also accurate colposcopy and histology. Both of these continued to be undertaken in Ireland and there is no performance monitoring data available for either. PPV is vulnerable to confounding by both colposcopists and histopathologists.
- PPV for low grade is not a standard measure in the UK. Documents available define it as the number of women having at least CIN1 after a cytology result of ASCUS or LSIL. As such the figure in 2009-10 seems implausible. Subsequently there has been a change to use APV, which is defined as the number of women with low grade cytology having high grade histology. This is a useful measure of undergrading. If PPV was being kept artificially high by only classifying as high grade very obvious high grade disease, this will show as a high APV. This was not the case here.
- RV (Referral Value) is a useful measure – it indicates the number of women referred to colposcopy to diagnose one case of CIN2+. An RV figure of 2.15 represents good specificity

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Differential Reporting between the Three Laboratories

A useful table of data was identified in a report to the QA group dated 2nd May 2016, it relates to the fourth quarter of 2015.

Laboratory:	Quest	MLP	CWUHU
Inadequate	0.9	1.9	1.8
Negative	89.6	88.5	85.2
ASCUS	4.3	3.1	1.7
LSIL	3.6	3.7	9.1
ASC-H	0.4	0.5	0.04
HSIL(m)	0.5	0.6	1.5
HSIL(s)	0.3	1.1	0.6
SCC	0	0.01	0
AGC	0.13	0.14	0.02
AGC favour neoplastic	0	0.01	0
Adenocarcinoma	0.01	0.02	0.07

This report also includes the following correlation data:

		PPV	APV	TPV
12/13	Quest	83	28	45
	MLP	90	34	65
13/14	Quest	82	22	41
	MLP	85	24	59
	CWUHU	83	25	64
14/15	Quest	86	30	43
	MLP	84	21	52
	CWUHU	83	28	47

Further information was sourced from the laboratory visits. Both Quest and MLP (incorporating TDL) had good internal data which they were able to submit. CPL data is not currently available.

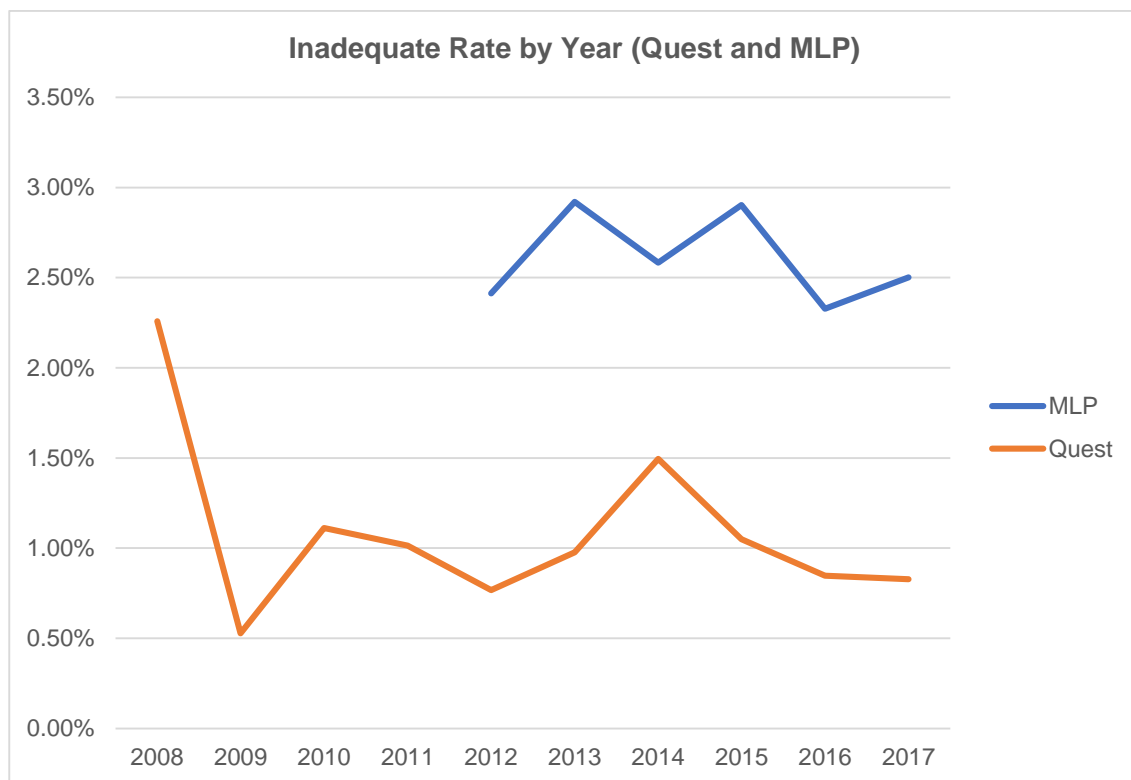
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Data Analysis

It is extremely difficult to make comparisons for data outcomes between providers because data has apparently not been collated and published by CervicalCheck. It has been necessary to trawl for this data through indirect sources and to rely on internal data collated by the labs but never authenticated by CervicalCheck.

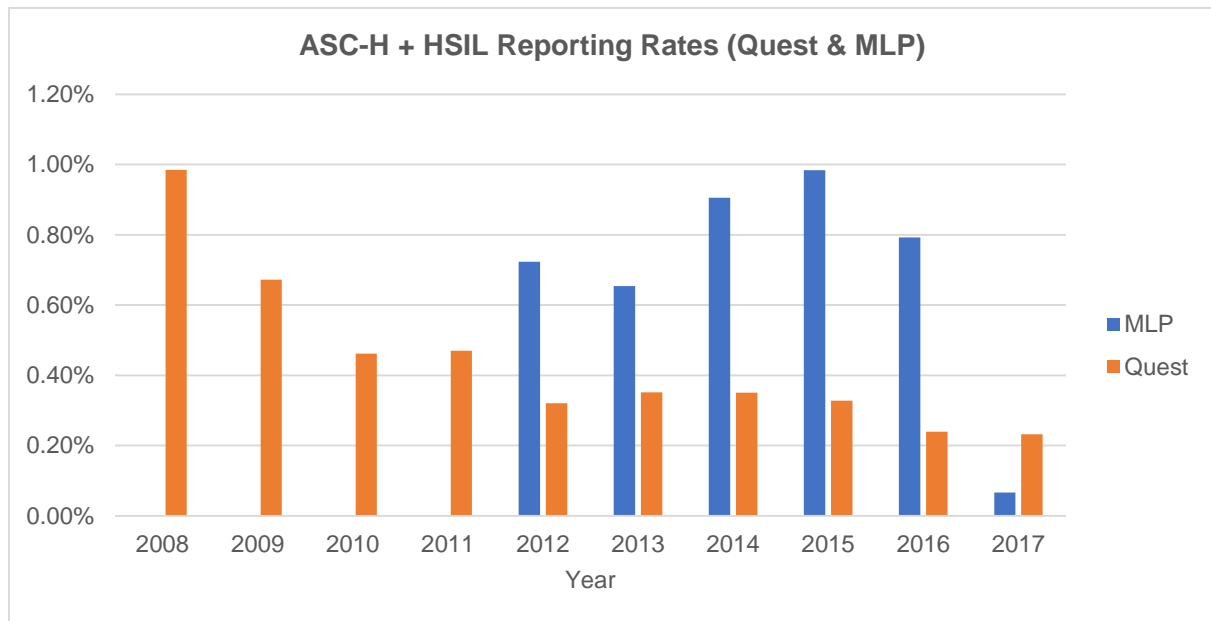
There appear to be variations between all three providers.

- Quest has a significantly lower inadequate rate than other providers, as can be seen in the following graph:

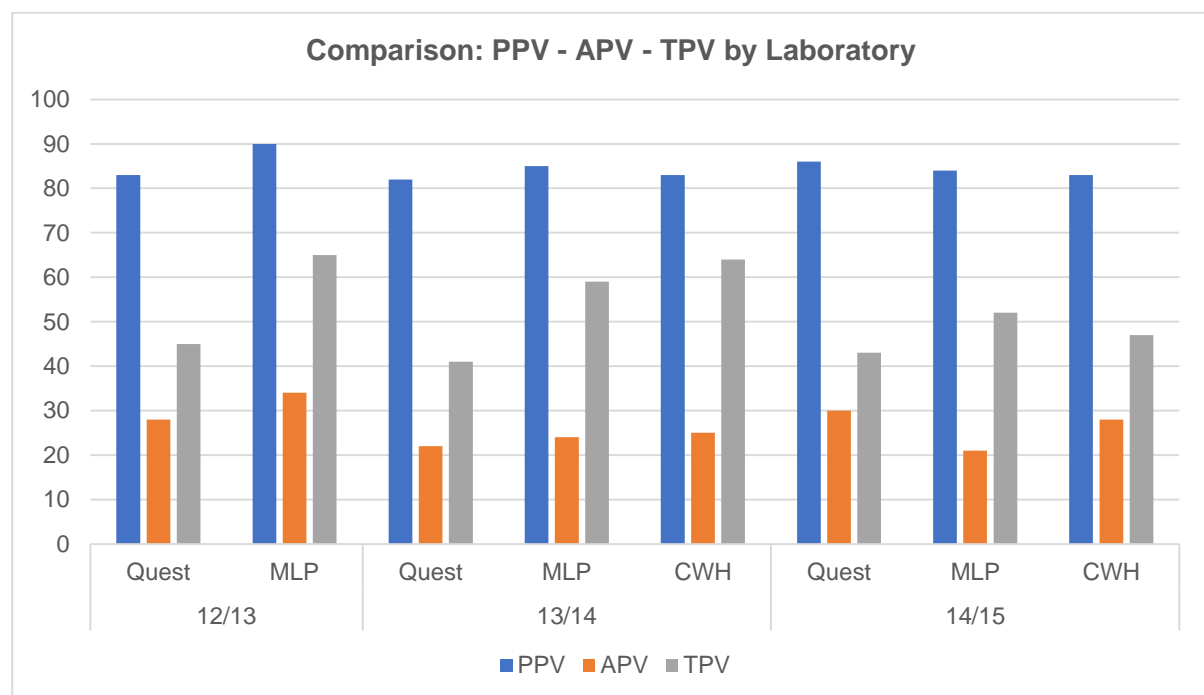


- ASCUS rate is highest in Quest, similar at MLP and much lower at CWIUH
- ASCUS + LSIL is significantly higher in CWIUH because the LSIL rate was very high and this was only partly compensated by the low ASCUS rate.
- CWIUH follows the UK practice and does not use ASC-H. This is reflected in the high grade rate, which is much higher at this site. Although no data exists to support this, it is also likely to be the case for work reported at TDL.
- However, combining the ASC-H, HSIL(m) and HSIL(s) figures to arrive at a total high grade rate does indicate a difference. The total figures are: Quest (TBR) 1.2%, MLP 2.2% and CWIUH 2.14%. The difference between Quest and MLP is consistent when other years are considered. These features are summarised in the graph below

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- Overall trends of a falling high grade rate are as expected due to increasing screening participation over multiple rounds and implementation of HPV triage in 2015.



- The correlation data shows some variation in direction from year to year. This is unlikely to be significant. Overall, all three sites show reasonably good positive predicted value (PPV), abnormal predicted value (APV) and total predicted value (TPV).
- However, these are likely to be an underestimate as all labs reported poor ascertainment by CervicalCheck of histology results and lengthy time intervals before histology is available.

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Appendix 2: Baylor College of Medicine Statements Regarding CPL Screenings

Statement #1 (dated May 1, 2018)

Baylor College of Medicine contracts with Clinical Pathology Laboratories, Inc., in addition to other laboratories, to read pap smears collected at Baylor outpatient clinics. We have reached out to Clinical Pathology Laboratories, Inc. to ascertain the accuracy of diagnoses for our patients and will do what is necessary to ensure the safety of our patients.

At this time it is not known how many of our patients could have been impacted by the possible inaccurate reading of pap smears. The College has launched a full review and any patients affected will be contacted.

Baylor College of Medicine provides medical direction of Clinical Pathology Laboratories, Inc.'s clinical laboratory operations in the greater Houston area, overseeing tests such as the analysis of blood, body fluid and urine specimens, for outpatient services at Baylor Clinic.

Pap smears taken at Baylor Clinic are sent to Clinical Pathology Laboratories, Inc. in Austin, and those at the Kirby Clinic Family Practice are handled by another laboratory. Pap smears from the Baylor obstetrics and gynecology department are handled by yet another large national laboratory.

Statement #2 (dated May 22, 2018)

CPL provided assurance that the guidelines followed in the United States offer additional protections and screening processes that were not available in the Irish screening program. Out of an abundance of caution, Baylor has been working with CPL to develop a plan to audit a statistically valid sample of pap smears to validate the test results. Any significant discrepancies will be addressed immediately with corrected reports and notification to the ordering physicians.

Statement #3 (dated June 28, 2018)

At the request of Baylor College of Medicine to ensure the well-being of its patients, and in response to adverse results of the cervical cancer screening program established and managed by the Irish government, Clinical Pathology Laboratories, Inc. (CPL), the screening laboratory for pap smear samples taken from patients seen at Baylor Clinic, conducted an audit of all samples screened by CPL in 2017 and 2018 to validate test results, totaling 237 pap tests.

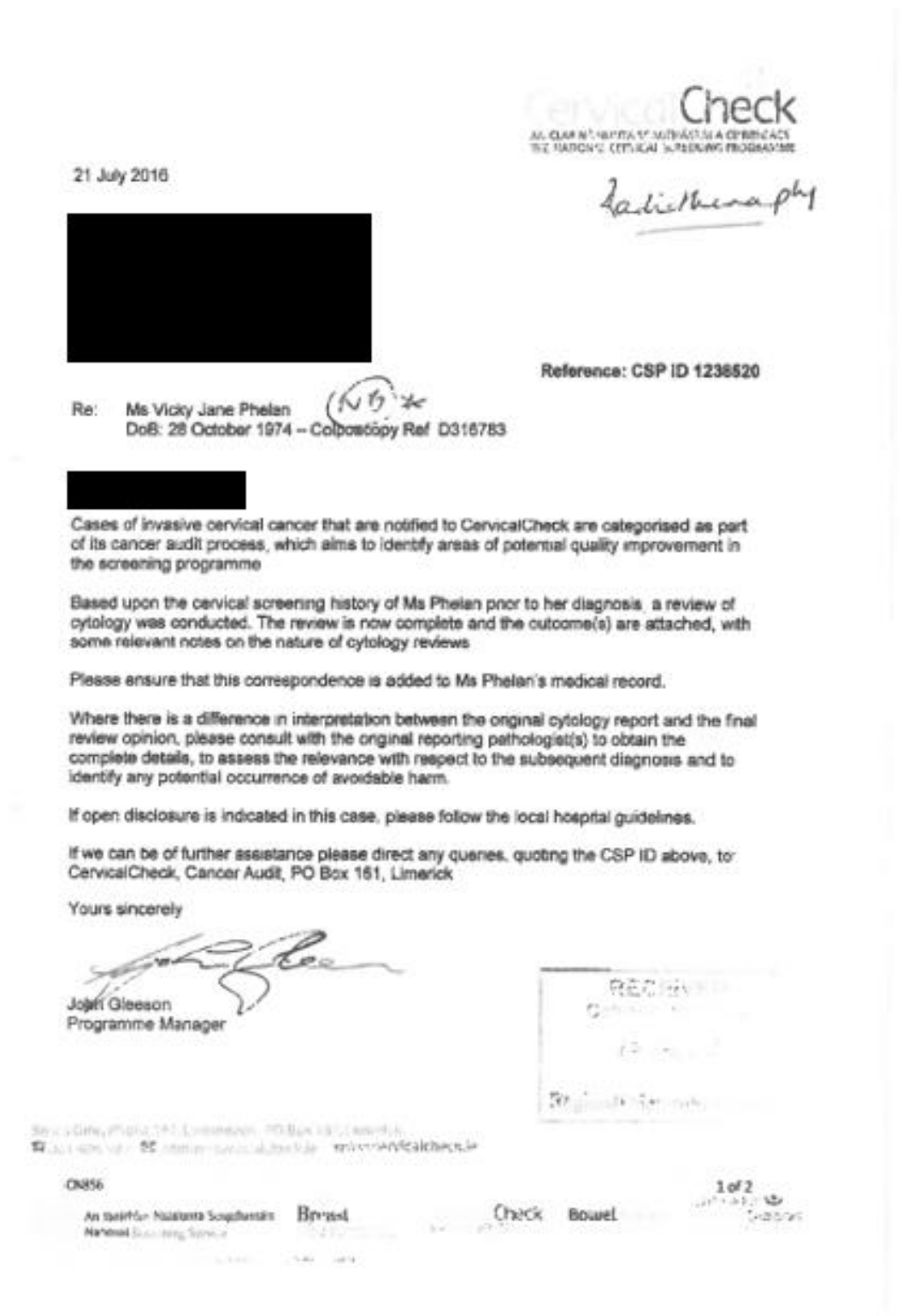
The audit completed by CPL showed diagnostic concordance in 233 of the 237 tests. The four inaccurate readings reported by CPL were minor in nature and highly unlikely to have negative clinical impact on individual patients. These four cases were corrected as necessary and reported to the ordering physicians.

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Given the low diagnostic error rate reflected in the CPL report, Baylor Clinic does not have plans to change screening lab providers at this time.

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Appendix 3: Letter from CervicalCheck to Vicky Phelan's Treating Clinician



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Appendix 4: Suggested Service Specification for a National Screening Committee

Context

As part of the Scoping Inquiry work, it was identified that a National Screening Committee (hereafter referred to as the Committee) would be advantageous and this is a draft service specification for consideration. It is drawn from international best practice, and reviews of other such services which identified features for improvement.

Introduction

This service specification draws on international best practice to identify the features of any service that are considered essential and would be necessary to run a national screening committee effectively and efficiently. This includes consideration of the costs of running such a service. The UK has a well-established National Screening Committee and the UK Code of Practice has been used as a basis for this document.

Purpose of the Specification

The purpose of this draft specification is to ensure that there is a consistent approach to the decisions to implement screening programmes across the country based on the best available evidence.

This specification is designed to outline the service and quality indicators adopted by the Department of Health so as to ensure a high standard of service is provided to the population. It therefore sets out specific standards.

The specification outlines the arrangements for commissioning the proposed Committee, to include:

- The aims of the Screening Committee
- The objectives of the Screening Committee
- The scope of the Screening Committee
- Description of the work of the Screening Committee
- Standards
- Work plan
- User involvement
- Indicative Key Performance Indicators
- The decision making process
- Accountability
- Membership

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The specification operates up to and including providing advice to the Department of Health. Subsequent agreement, funding, management and quality assurance of any screening programme are outside of the scope of this specification.

The service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, or the work undertaken by HIQA. In the event of new evidence on best practice in the development of screening policy, the specification could be reviewed and amended as rapidly as possible.

Aims and Objectives of a National Screening Committee

Aim

The aim of the Committee is to recommend population-based screening programmes, using the best available evidence to reduce the incidence of and mortality from disease.

Objectives

In accordance with best practice and in order to ensure appropriate use of finite resources, the National Screening Committee (hereafter referred to as the Committee) will:

- Effectively implement an agreed methodology for accepting applications to consider new or revised screening programmes;
- Agree and implement a prioritisation process for the consideration of new or revised screening programmes;
- Develop and implement a robust and transparent system to consider potential population-based screening programmes;
- Clearly communicate the recommendations and the reasoning to the Department of Health, stakeholders and the public on the outcomes of deliberations;
- Review any advice routinely every three years, or beforehand, if significant new evidence becomes available.

Scope of the National Screening Committee

The Committee will be an independent Committee responsible for considering population-level screening programmes in Ireland.

The scope of the Committee will include work prior to evidence being submitted to the Committee, the work of the Committee and the communication of the work of the Committee.

The Committee will undertake a horizon scanning function, working with stakeholders to understand potential future demands and plan a rolling programme of evidence reviews to assess the evidence.

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The Committee will recommend evidence based, cost effective, population level screening programmes that minimise the incidence and mortality from disease.

The Committee will engage in transparent decision making and communicate effectively with a variety of audiences including stakeholders, the Department of Health, the HSE, Government Ministers, patient groups and the public, when describing the Committee's recommendations.

A clear process to agree which potential screening programmes are included or not in the scope will be established at the outset, and will be agreed with all other relevant agencies. Where there is doubt, the Department of Health will make this decision.

Description of the Committee's Work

The criteria for establishing if a screening programme should be recommended will be established at the first meeting of the Committee. It is expected that this will be the primary focus of the Committee's first meeting. This will be based on international best practice, including the World Health Organization's Guidelines.

The Committee will then meet four times per year to consider the potential harms and benefits of each new or revised screening programme against the agreed criteria, and will make recommendations to the Department of Health.

The Committee shall identify a range of potential stakeholders who should be involved in providing evidence to the Committee and shall develop relationships with the appropriate stakeholders relevant to the programme of work each year. Some stakeholders representing wide groups of people may have ongoing relations with the Committee.

The Committee will communicate its recommendations to the Department of Health, stakeholders, and the public after each meeting; taking time to ensure communications are in plain language and can be understood by the general population.

Standards

The Committee shall consider and make recommendations on a minimum of four screening programmes each year.

The Committee shall ensure that there is direct input from the third sector (e.g. patient support groups; charity organisations; advocacy groups etc.) in each case evaluating whether the proposed tests and treatments are acceptable to the public.

The Committee shall maintain professional standards and be able to provide an audit trail for each decision made and the reasoning.

Draft minutes of each meeting will be placed in the public domain, e.g. on the dedicated website within ten working days of the Committee sitting. The minutes shall be agreed at the following meeting and then placed in the public domain within three working days.

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All papers considered by the Committee will be placed in the public domain ten working days after the meeting has taken place. The Committee shall publish all papers it has considered, and those invited to provide papers for the Committee will be made aware of this.

The Committee will produce an annual report, together with a forward plan of new or revised screening programmes that will be considered in the following year.

The Committee will hold a public meeting following the publication of the Annual Report and will allow time to take questions from the public and stakeholders.

Work plan

The programme of work for the first year shall be proposed by the Department of Health and agreed by the Committee. In subsequent years the work plan will be developed by the Committee and considered and approved by the Department of Health.

The Committee will in the first year establish a clear system of prioritising potential and revised screening programmes. The prioritisation process for consideration of screening programmes should be clear and will include considerations of urgency, need, public health impact, variation in care, current practice, timing of most recent reviews, availability of new evidence, sufficiency of evidence, interests of the public and professionals.

Clinical and Corporate Governance

The Committee will be making recommendations to the Department of Health which should have a significant impact on the screening programmes offered in the State. It is therefore important that the Committee establish clear policies and procedures to manage clinical and corporate governance. This will be established as part of the Terms of Reference of the Committee, once the host for this independent Committee is identified.

User involvement

The Committee is independent and will need to develop strong working relationships with multiple stakeholders, including patient groups and the third sector. This should be a key function of the Committee. Once the work plan for the first year is agreed, an exercise to scope potential stakeholders should be drawn up and Committee members will be asked to forge relationships with these groups as appropriate. A formal engagement plan for the Committee should be drawn up. Regular feedback should be sought and recorded to assure the Department of Health of high quality engagement in the process.

Key Performance Indicators

The Key Performance Indicators (KPIs) for the Committee will be set between the Department of Health and the Committee on an annual basis and should include aspects of both quality and quantity to ensure that the work required is being progressed to a satisfactory standard. Indicative KPIs are outlined in Table 1.

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Objective	Standard	Reporting Period	Source of Information
Effectively implement an agreed methodology for accepting applications to consider new or revised screening programmes.	Agree clear method for requesting cases and a subsequent prioritisation process for accepting applications within six months. Implementation of methodology within six months.	At six months, and 12 months.	Minutes and Papers of Committee to show discussion and implementation in practice.
Develop and implement a robust and transparent system to consider potential population-based screening programmes.	Methodology based on international best practice identified and adopted within six months. Implementation of methodology by Committee within six months	At six months, and 12 months.	Minutes and Papers of Committee to show discussion and implementation in practice.
Clearly communicate recommendations and the reasoning to the Department of Health, stakeholders and the public.	Develop a communications strategy for the Committee and show how this has been implemented in practice	At six months, and 12 months.	Document the communications Strategy and show how it is being implemented, by evidence of proactive and substantial engagement with stakeholders and the public on relevant topics
Review all advice routinely every three years, or before if significant new evidence becomes available.	Develop a forward plan for all those cases reviewed in year 1 to be re-assessed in year 4.	At 12 months	Clear forward development plan for re-assessment together with streamlined process, if appropriate.
Establish functioning Committee with clear and agreed Terms of Reference based on international best practice.	Fully appointed membership, with range of skills, all members have had induction training and have a training plan for the year.	At six months, and 12 months.	Committee membership list with skills mix. Training undertaken and further sessions planned to meet the needs of the Committee.
Engage with relevant stakeholders depending on the agreed work plan.	Develop and deliver an engagement strategy.	At six months, and 12 months.	Engagement Strategy. Feedback from the Stakeholders on the quality of engagement.

Table A1-a: Indicative Year 1 Key Performance Indicators

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Data Reporting

Data on the KPIs will be presented from the Committee to the Department of Health at six month intervals and will form part of the annual review process at 12 months. Data will be supplied to the Department of Health in the form of a report twice a year in the first year, and thereafter as agreed between the two parties. This should be no longer than every six months in the first instance to ensure that the Committee is able to undertake the work as planned. Issues that prevent the Committee from undertaking its work should be shared with the HSE in writing as an 'exception report' within one month.

Continual Service Improvement

The Committee will be expected to commit to the principle of continuous improvement. It is acknowledged that in the first year there will be significant learning for the Committee in fulfilling its function effectively.

Lessons learned by the Committee should be clearly documented, and actions taken to address the challenges encountered should form part of the annual report, which should not only highlight the successes of the Committee, but the obstacles it encounters and the measures taken to address them.

Decision-Making Process

The Committee will be responsible for making recommendations to the Department of Health on population level screening programmes after each meeting.

A quorum is reached when at least half of the members are present. Only members of the Committee contribute to the quorum. In the event of the meeting being inquorate, discussion can take place but no Committee decisions can be made.

Open and frank discussion will be encouraged. It is recognised that advice includes expert judgement in addition to objective or factual information, and wherever possible the degree of certainty and the rationale for judgements will be recorded.

The public will be excluded from Committee meetings, however, senior level observers from a range of professional bodies shall be invited to each meeting provide a quality assurance role, they will be required to comment on the quality of the discussion and provide an external review of the functioning of the Committee at the end of each meeting. A summary of this shall be included in the minutes.

The Committee should seek to obtain a unanimous view for its recommendations. Where there is disagreement the Chair should explore and attempt to resolve reasons for disagreement. The Chair can exercise the option to defer decisions to a future meeting. Where consensus cannot be reached, and a vote is required, a simple majority of the Committee voting members (excluding the Chair) is required. The Chair will cast their deciding vote only when a majority is not achieved by the other voting members.

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Accountability

The Committee will be accountable to the Department of Health, which will agree the forward work plan for the Committee on an annual basis.

The Department of Health will review progress formally against objectives set out in the work plan in an annual appraisal meeting with the Chair of the ROI Screening Committee.

The Committee shall supply to the Department of Health a six-month progress report and an annual report.

The Terms of Reference for the Committee should be reviewed by the Committee and agreed by the Department of Health at least every three years.

Committee Membership

The following range of expertise is required on the Committee:

- Public Health (screening)
- Ethics
- Representation of Patient and Public Voice
- Health Economics
- Epidemiology
- Medico Legal
- Social Scientist
- General Practice
- Paediatrics and Child Health
- Obstetrics
- Cancer
- Genetics
- Laboratory Services
- Nursing and Midwifery

Where necessary to deal with screening programmes beyond the expertise of the group additional members may be co-opted to provide advice, but will not be voting members.

The Committee will consider many different social, ethical, and legal issues associated with screening, particularly noting that new programmes involving genetic screening and technologies may produce complexities that could be novel for society. While these are not confined to genetic screening, relevant issues include consent and autonomy, discrimination and stigmatisation, issues around choice, privacy and confidentiality, data ownership, storage and sharing. It is vital that alongside the scientific and clinical evidence, these issues receive attention from the Committee in an expert and explicit way.

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Roles

The Chair and members are appointed as individuals to fulfil the Terms of Reference of the Committee, not as representatives of their particular professions, their employer or any interest group.

The appointment process and length of membership will be in line with the Guidelines on Appointments to State Boards and the Public Appointment Process.

Honorary contracts shall be issued to all members of the Committee, this will outline the nature of the role, the expected standards, and any processes which must be adhered to relevant to the host organisation.

Chair of the Screening Committee

The position of Chair of the Committee should be filled through an official Public Appointments' Procedure.

The Chair is responsible for providing effective leadership to the Committee. The Chair will ensure that accurate, timely, clear information is provided to members and that the minutes of the meetings accurately record the discussions held and the advice agreed.

The Chair is responsible for ensuring appropriate membership with the right balance of skills. The Chair must ensure that the Committee has a culture of valuing different perspectives and encouraging full engagement in collective consideration and discussion of the issues.

The Chair is responsible for ensuring that the Committee does not exceed its terms of reference.

The role of the Chair necessitates that he/she cannot have any interests that may conflict with his or her responsibilities to the Committee. Therefore, the Chair cannot have interests that could conflict with the issues under consideration by the Committee. If the Chair has an unresolved conflict of interest, then he/she shall step aside until it is resolved. The Vice Chair will deputise for the Chair in these circumstances.

There may be times when urgent advice is required. On such occasions the Chair may, on behalf of the Committee, provide such advice. The Committee will be updated at the earliest opportunity of any advice provided.

The Chair is responsible for taking action when members' attendance is poor, and will conduct an annual appraisal of performance with each member of the Committee on the fulfilment of their role.

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Vice Chair

The Vice-Chair is elected by the membership. The Vice-Chair will be responsible for chairing meetings and providing leadership if the Chair is not able to chair the meeting for any reason. The Vice-Chair should have appropriate expertise in screening.

Membership

Members must at all times:

- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide;
- abide by the principle of collective responsibility, stand by the recommendations of the Committee and not speak against them in public;
- be accountable for their activities and for the standard of advice they provide.

Members and observers of the Committee must declare their relevant personal and non-personal interests at the time of their appointment, and annually thereafter, or sooner if their circumstances change.

It is the responsibility of each member to indicate if they have an interest in any item of business on the agenda of a meeting of the Committee prior to the meeting directly to the Chair. The Chair will then determine whether a member should take part in any discussion or decision on the issue, and may in some circumstances seek additional expertise from a co-opted member to replace the expertise of the member for this item. This will be clearly documented in the meeting minutes.

Members are expected to attend all meetings in person. However, when this is not possible digital communications will be made available. The attendance and contribution of members of the Committee will be subject to annual appraisal by the Chair.

Members who speak at conferences, teach, run seminars or have public speaking arrangements with the media should make clear at the outset whether they are speaking in a personal capacity or as a member of the Committee.

Members may not send representatives if they are unable to attend a meeting.

Appointments may be suspended or terminated, in the event of a member failing to fulfil his or her obligations, or for conduct which renders the member unfit to remain in office. Members may also resign from their office.

Diversity of the Committee

Selection and recruitment of Committee members will take account of the diversity of the group in comparison to the wider population, and the balance of age, ethnicity, disability, gender and other protected characteristics under the Irish Rights and Equality Commission Act, 2014.

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Training of the Committee

The skills of the Committee will be formally recorded by the Secretariat to help identify its training needs. Members will require training in issues such as genetics, ethical, legal and social issues in order to deal effectively with the work of the Committee.

All members will receive induction training and support from the Chair to fulfil their role. Training and development opportunities will be offered to all members where appropriate as part of the annual appraisal process.

Indemnity

A Committee member may be personally liable if he or she makes a fraudulent or negligent statement which results in a loss to a third party; or may commit a breach of confidence under common law or a criminal offence under insider dealing legislation, or if he or she misuses information gained through their position or breaches confidentiality. However, the host organisation will ensure that individual Committee members who have acted honestly, reasonably, in good faith and without negligence will not have to meet out of their own personal resources any personal civil liability which is incurred in the execution or purported execution of their Committee functions.

Remuneration

Members are not remunerated for their work for the Committee. They are eligible to claim expenses in accordance with rules of the host organisation for travel, subsistence and overnight accommodation.

Secretariat

The primary role of the Secretariat is to support the Committee by assembling and analysing information and recording conclusions of meetings. The Secretariat is impartial and respects the Committee's independent role.

The Secretariat will manage the collation of specific expert clinical advice, and will manage the process of allowing interested stakeholder groups to feed into the process of decision making.

The Secretariat will ensure that the proceedings of the Committee are documented to provide a clear audit trail showing how the Committee reached its decision.

The Secretariat will draw up appropriate procedures for handling sensitive information. These procedures will be communicated to potential providers of sensitive information, so that material is only withheld from public release where it would be exempt under the provisions of Freedom of Information legislation.

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The Secretariat will deal with initial media enquiries, and direct them appropriately. Members of the Committee may be asked, by the Secretariat or Chair to speak to the media on a matter pertaining to the work of the Committee.

The Secretariat will deal with complaints, and direct them appropriately. Members of the Committee may be asked, by the Secretariat or Chair to prepare a response to any complainant on a matter pertaining to the work of the Committee.

The Secretariat will provide proactive communication services and functions to the Committee, including the development and maintenance of the Committee's webpage, and all social media outlets.

Appeals Process

Since the Committee is an independent advisory body that provides advice, there is no appeals process provided for on the advice given. Statements on any disagreement with the recommendations will be shared at the start of the next meeting to keep the Committee abreast of public and professional opinion.

Costs

The Committee will need an adequate budget to allow it to achieve the aims and objectives set. It will need support from the secretariat to achieve the smooth running of this important body that will be making recommendations that will have an important impact on the health and well-being of the population of Ireland.

The UK equivalent body has an annual budget of £1,866,400 (Annual Report 2016/17). The budget for the Committee will need to be adequate to obtain the support and expert advice required to make decisions that impact at population level. Funding would be needed to support significant literature reviews from independent contractors such as University or Research Groups, and to provide adequate secretariat and training support to the Committee members.

The development of this specification drew on a number of sources including:

- *Annual Report of UKNSC 2016/17. Screening in the UK: Making Effective Recommendations 1 April 2016-31 March 2017. Public Health England Gateway ref: 2017440*
- *Review of the UK National Screening Committee (UK NSC) Recommendations, June 2015. Public Health England Gateway ref: 2015139.*
- *Review of the UK National Screening Committee (UK NSC) Summary of Consultation Responses, June 2015. Public Health England Gateway ref: 2015139.*
- *Seedat F, Cooper J, Cameron L, Stranges S, Kandala NB, Burton H, Taylor-Phillips S. International comparisons of screening policy-making: A systematic review, 2014.*
- *UK National Screening Committee, Code of Practice, Published 2nd November 2015 Last updated 24th October 2016. Public Health England Gateway ref: 2015139.*